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Brown, Alison (2017) *The application of relaxation for mothers expressing breast milk for their infant in the neonatal unit: A feasibility study and clinical research portfolio.* D Clin Psy thesis.

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The Application of Relaxation for Mothers Expressing Breast Milk for Their Infant in the Neonatal Unit: A Feasibility Study and Clinical Research Portfolio

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Submitted in partial fulfilment of the requirements for the degree of Doctorate in Clinical Psychology

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September 2017

Acknowledgements

I would firstly like to thank the mothers and staff in the Neonatal Unit who helped to make this project possible.

I would also like to offer my gratitude to Dr Alison Jackson, Dr Joan Burns and Dr Marisa Forte for giving me the opportunity to explore this area of research and offering your support throughout the process. Thanks to Dr Caroline Haig for your help with statistics and to Librarian Sonny Maley for your support with the development of my search strategy.

Sincere thank you to Harriet Bowyer for reviewing the studies in my systematic review, it has been fantastic to work with you in our study group throughout the course. I would also like to thank my friend and colleague Dr Kim Campbell for your support in the development of the themes in the MRP and of course your words of wisdom over the years.

Getting to this stage in my career would not have been possible without the incredible, unwavering support provided by my Mam and Dad. Your ability to listen, understand and keep me smiling is massively valued. Finally, I would like to thank Andy for your unfailing emotional and practical support. Thank you for turning the tough days around with positivity, love and laughter!

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Chapter 1: The Benefits of Relaxation for Parents with Infants in a Neonatal Unit: A Systematic Review

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Word Count: 6662

Prepared in accordance with the Journal of Reproductive and Infant Psychology guidelines for submission

Disclosure Statement: The author reports no conflicts of interest.

Abstract

Objective: To determine how parents could benefit from the use of relaxation when they have an infant admitted to a neonatal unit (NNU).

Background: An admission to the neonatal unit can impact upon a parent's development of their role as well as on their stress levels. Stress can negatively impact on factors such as parent's mood, sleep quality and physiological wellbeing. Relaxation is a commonly used early intervention approach to manage the effects of stress and anxiety.

Methods: The search included a review of Medline, Embase, Psychinfo and CINHAL databases, from the start of the database to March 2017. Studies were reviewed independently by two assessors using the Cochrane Risk of Bias tool.

Results: From 462 studies identified from the search, 4 were selected for review. Three areas (expressing breast milk, stress levels and sleep quality) have been examined to determine if the use of relaxation benefitted parents with an infant in the NNU. Studies generally had a low or unclear risk of bias.

Conclusion: There was promising data to suggest relaxation could be beneficial for milk production and sleep quality. There was limited data to suggest relaxation could help parents manage stress. Caution needs to be applied in the interpretation of the effectiveness of the intervention due to the limited number of studies and multiple factors impacting on parents during this time. Given the effectiveness of relaxation with populations outwith the NNU it is recommended that further research into the potential benefits of relaxation which account for the multiple variables impacting on parents during this time is conducted.

Keywords: Relaxation, Parents, Neonatal Unit, Milk, Stress, Sleep.

Introduction

Preterm birth and an admission to the Neonatal Unit (NNU) can impact on the physical health of the infant and have a psychosocial and emotional impact on parents (Obeidat, Bond and Callister, 2009). An admission to the NNU occurs when an infant is born prematurely, at a low birth weight or experiences medical complications. The birth can be fast, unexpected and at times traumatic for mothers (Fenwick, Barclay and Schmied, 2008). Fathers may experience anger, stress and anxiety in trying to establish their role as parent, partner and provider of support (Deeney et al., 2009; Ionio et al., 2016).

Being a parent in a Neonatal Unit

Mercer's model of "Becoming a Mother" (Mercer, 2004) describes the developmental process that mothers may encounter during a healthy pregnancy and the infant's first months. It outlines 4 stages of psychosocial adjustments. It is suggested by Mercer that in the third trimester mothers experience the psychological adjustment to becoming a mother (Mercer, 2004). While in utero, mothers start to contemplate what their infant will be like (commitment and preparation). When infant arrives they learn to be a mother through practice and observing others (acquaintance, practice and physical restoration). Mothers then develop their own mothering style (approaching normalisation) and finally they adapt to fit their infant's needs into their life (integration of maternal identity) (Mercer, 2004). This process is interrupted when a baby is born preterm or admitted to the NNU. A grounded theory analysis of 28 Australian mothers with infants in the NNU suggested an alternative developmental model of becoming a mother (Fenwick et al., 2008). They suggest mothers experience 3 main stages while in the NNU: just existing, striving to be a mother, and trying to establish competence. During these stages mothers were oscillating between feeling

connected to their infant and struggling to be a mother (for example, experiencing negative emotions, self-blame, and feeling labelled due to their emotional experience) (Fenwick et al., 2008).

The psychological, physical and emotional impact experienced by parents in the NNU understandably varies for individuals. While most of the literature explores maternal experience, there is growing knowledge of the impact on both parents. Fourteen qualitative studies of parents in the NNU highlighted that they experience feelings of stress, parental role strain alongside ambivalence, despair and lack of control (Obeidat et al., 2009).

Unique environmental factors contributed to stressful experiences for parents such as the noisy setting, medical equipment, medical language, the constant presence of medical staff and other patient and family clusters (Nyqvist and Engvall, 2009).

In a sample of 86 mothers and 41 fathers, 81% of mothers and 66% of fathers experienced clinically significant levels of arousal within the first week of their infant's admission (Lefkowitz, Baxt, & Evans, 2010). Thirty days later, levels of arousal remained clinically significant for 30% of mothers and 28% of fathers. It is recommended that clinicians consider that parental reaction in the NNU can vary along a continuum of distress (Elmir et al., 2010) and can appear transient over time (Fenwick et al. 2008).

The impact of distress

As parental experiences of stress and distress can vary within the NNU, it is important to consider how this may impact on parental functioning. Stress and anxiety can impact on cognitive functioning and present physically with an increase in heart rate, blood pressure, cortisol levels, fatigue, irritability, muscle

aches, and difficulty with sleep (American Psychiatric Association, 2013; Mental Health Foundation, 2017).

All new parents may experience stress and its effects as they try to develop confidence in their role. For parents with infants in the NNU the occurrence of stress is likely to be prolonged due experiential factors related to the NNU. For example, it was identified that mothers of healthy infants initially experienced sleep disturbance which naturally reduced over time (Filtness, Mackenzie, Armstrong, 2014). For parents with infants in the NNU the separation, the changing health status of their infant and the stress of trying to develop their role had a negative impact on sleep (Heidari, Hasanpour and Fooladi, 2013). Furthermore, stress can impact on maternal physiological processes such as producing breast milk (Lawrence and Lawrence, 2011) which can provide their vulnerable infants protection from infection (Underwood, 2013). It has been suggested that professionals should support parents to reduce anxiety and stress, and help the development of their role while the infant is in the NNU (Galeano and Carvajal, 2016).

Interventions

A common psychological approach to reduce anxiety and stress is to use relaxation techniques. There are different approaches to relaxation, such as autogenic training (training the body to respond to verbal commands to stimulate calm), guided imagery (GI), diaphragmatic breathing and progressive muscular relaxation (PMR). A systematic review of 19 studies (N=793) that explored the use of relaxation globally between 1997 and 2007, concluded that relaxation consistently reduced anxiety in adults with a medium to large effect size (Manzoni et al., 2008). Manzoni et al. (2008) identified that PMR and autogenic training

were most effective for managing the experience of anxiety. A systematic review of 13 studies that explored relaxation used during pregnancy, reported that relaxation consistently improved mothers' psychological well-being and lowered their heart rate and blood pressure (Fink et al., 2012). Two randomised control trials, in Greece (N=54) and in Iran (N=120) identified that parents who received relaxation and had a child in hospital, had a greater reduction in anxiety and tension compared to controls (Tsitsi et al., 2017; Poodineh, 2017).

Emerging literature appears to be testing the hypothesis that relaxation may be useful for parents with an infant in the NNU. Research to date has explored the impact of relaxation on maternal expressed breast milk (MEBM) (Feher, et al. 1989; Keith, Weaver and Vogal, 2012), anxiety (Shaw, et al. 2013) and parental stress management (Fotiou et al., 2016)**.** At a time of limited resource within health services, knowledge of the functions and effectiveness of a low cost intervention could be beneficial for both parents and health care providers. Therefore, this systematic review aims to determine how parents could benefit from the use of relaxation when they have an infant admitted to the NNU.

Research Question:

(1) How could parents benefit from the use of relaxation when they have an infant admitted to the NNU?

Method:

Search Strategy / Procedure:

The final search strategy (Appendix 1.2) was developed following consultation with a University of Glasgow Librarian. The "PICOS method"

(Moher et al., 2009) (with the "outcome" to be determined) was used to define the search criteria:

- Population- Parents.
- Intervention- Relaxation.
- Condition- Infant admitted to Neonatal Unit.
- Outcome- (to be determined).
- Study Design- Randomised Control Trial (RCT).

The search reviewed Medline, Embase, Psychinfo and CINHAL databases, from the start of the database to March 2017. Boolean phrases of "AND" and "OR" were used to connect search terms. Both MeSH terms and key words searches were employed to explore the titles and abstracts of the literature.

Studies were included if:

- Participants were biological parents (mother, father or both) of infants admitted to a NNU.
- Relaxation training was the main component of the intervention (when relaxation was named as the intervention in the method).
- The study was a RCT.
- Quantitative data was collected.
- The study was published in English.

Studies were excluded if:

- Relaxation was a component of another intervention (e.g. a Cognitive Behavioural approach).
- The relaxation was completed prior to the birth of the infant.

- The data was presented in a review or a poster presentation.

Once duplications of findings were removed, there were two levels of assessment to determine the articles' eligibility. First, study titles and abstracts were reviewed and those that did not meet the criteria were removed. The remaining papers were then accessed and assessed for eligibility. A hand search of the reference lists of the articles selected from the electronic search was conducted to identify any studies which may have been overlooked. Once articles were selected all papers were rated by the author and a colleague. All discrepancies (14%) were discussed and a final score was agreed upon.

Quality Assessment Tool:

Risk of Bias

Studies were reviewed adhering to best practice guidelines (Moher et al., 2009) using the Cochrane Risk of Bias tool (Higgins et al., 2011a). The Risk of Bias tool requires assessors to consider the possibility of bias in the research methods and results, rather than the quality of how the research was conducted (Higgins, Altman and Sterne, 2011b). Using the tool, assessors allocate a judgement of low, high or unclear risk to 7 items (6 domains) where bias could occur. These items (and domains) are:

- random sequence generation (selection bias),
- allocation concealment (selection bias),
- blinding of participants and personnel (performance bias),
- blinding of outcome assessments (detection bias),
- incomplete outcome data (attrition bias),
- selective reporting (reporting bias),

- other sources of bias (other bias).

Assessors are also required to justify their judgement of bias based on the report, or additional information provided by authors. All the authors in the selected studies were contacted and asked to provide additional information when judgements were "unclear". As they did not respond within the time frame, judgements were based on information in the published reports.

Synthesis

Judgements and justification of the risk of bias were extracted into RevMan (RevMan, 2012). No meta-analysis was completed due to the limited data and variation in outcomes. Data was instead extracted and a descriptive synthesis is provided. When significant results were reported, the effect size (*d*) was calculated (Cohen, 1988) by the assessor. When studies reported standard errors they were transformed to standard deviations for this calculation (Higgins and Deeks, 2011).

Results

General findings

As indicated in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) diagram (Moher et al., 2009), 462 studies were identified from the electronic search and one additional study was identified from a hand search. Four studies were eligible to be included in the synthesis (Figure 1)**.** Two studies that used relaxation interventions with mothers with infants in the NNU were excluded because they used a repeated measures single case design (Schaffer et al., 2013; Feijs et al., 2013). According to the Cochrane general hierarchy of

study designs (Ryan et al., 2013), the single case design cannot control for factors related to selection bias and therefore were excluded.

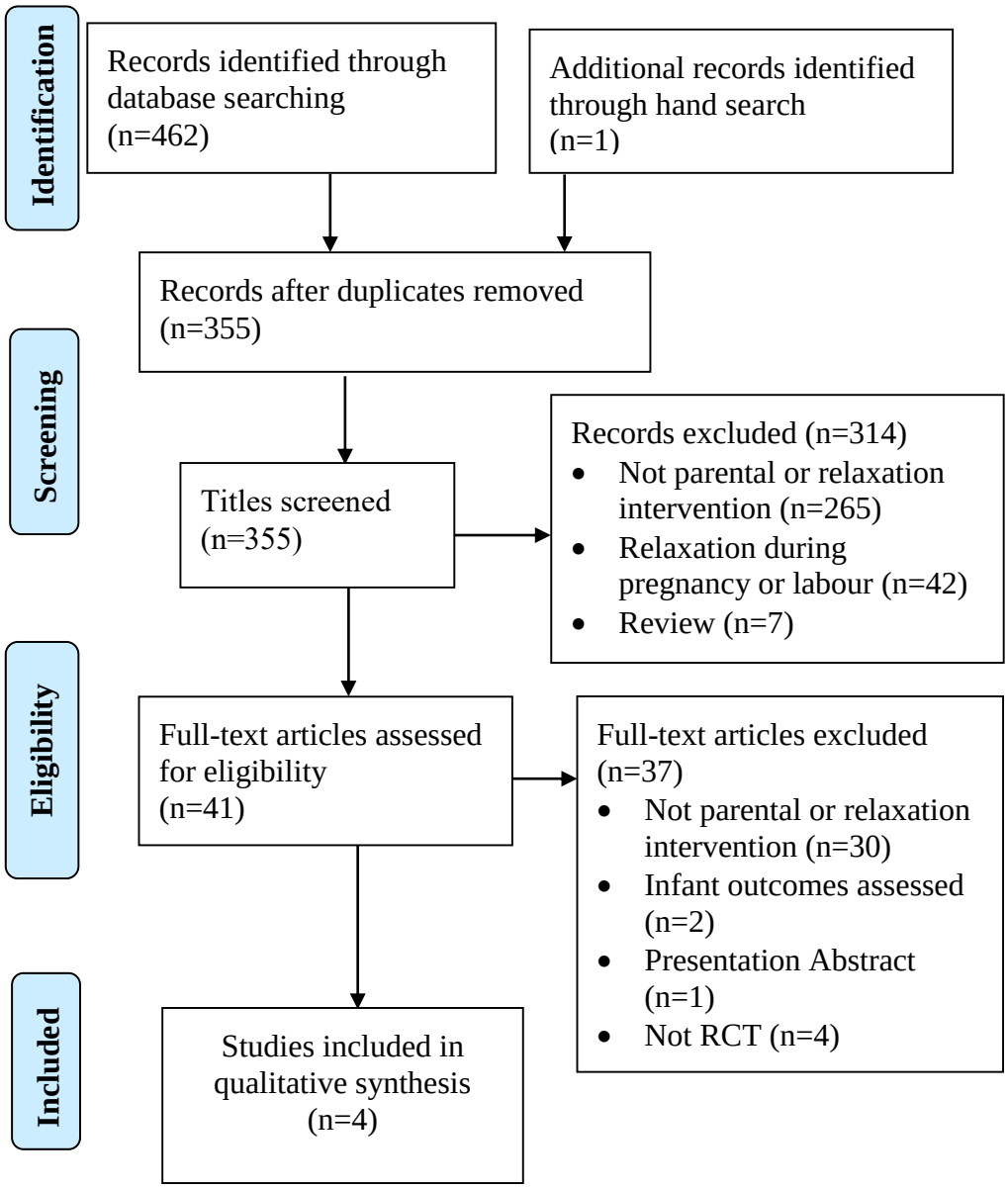


Figure 1. PRISMA diagram of selection process

Risk of Bias

Studies generally had a low (39.3%) or unclear (39.3%) risk of bias. Keith et al. (2012) and Fotiou et al. (2016) confirmed adequate methods of randomisation. Three studies were unclear or had high risk of bias in allocation

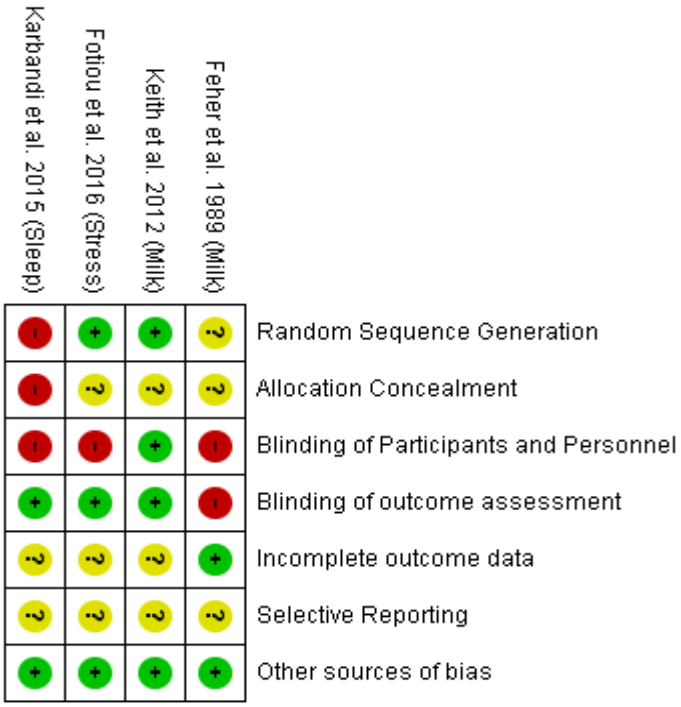
concealment. None of the studies reported what information participants received at the point of allocation (Table 1).

Cochrane's guidance encourages reviewers not to view studies as poor quality when there are methodological and ethical challenges for participants to remain blind (Higgins, et al., 2011b). Therefore, while participants in Keith et al. (2012) were not blind, it is unlikely that this would impact on the outcome so it was judged to be at low risk of bias. In the other studies because participants and researchers were not blind and it appeared possible that it could impact on outcomes, they were judged to be at high risk of bias.

Only one study included explanations of missing data in the context of their allocation (Feher et al., 1989). Two studies did not specify which groups participants were allocated to when they did not complete the study (Karbandi et al., 2015; Fotiou et al., 2016). Discrepancies between participant numbers in the text and tables were not acknowledged by Keith et al. (2012).

All studies were deemed to have an unclear risk of bias for selective reporting and a low risk of bias from other sources. A full description of judgements is available in Appendix 1.3.

Table 1. Risk of bias judgement for each article and item



Outcome

The effect of relaxation on MEBM volume and fat content was explored in two studies (Feher et al., 1989, Keith et al., 2012), sleep in one study (Karbandi et al., 2015) and stress in one study (Fotiou et al., 2016) (Table 2). One study explored relaxation with both parents (Fotiou et al., 2016), while three studies looked at the impact on mothers. All studies utilised an audio relaxation practice through a personal device (CD or mp3). Descriptions of the intervention can be found in Table 3.

Maternal Expressed Breast Milk

Participants used a combination of PMR and GI for seven (Feher et al., 1989) and fourteen days (Keith et al., 2012). Feher et al. (1989) recruited mothers three to five days postpartum, while Keith et al. (2012) reported the mean age of infants in each group ranged from *M*= 1.4 days (*SD* =0.6) to *M*= 2.1 days (*SD* = 2.3). The gestational age range was similar across studies (Table 2). Unlike Keith

et al. (2012), Feher et al. (1989) accounted for social variables such as education and family income, which were not statistically different between the two groups.

Keith et al. (2012) compared different relaxation conditions (verbal relaxation; verbal relaxation, plus music; and verbal relaxation, plus music, plus images) to treatment as usual (TAU). Feher et al. (1989) compared TAU with verbal relaxation and music. At day seven there was between a medium and large significant positive effect (d =0.64) of relaxation on MEBM quantity compared to controls (Feher et al., 1989) (Table 3). At day fourteen there was a large effect of all relaxation conditions compared to controls (Keith et al., 2012). The greatest positive effect on quantity (d= 2.30) occurred when mothers listened to verbal relaxation, music, and viewed images of their infant. Feher et al. (1989) reported a dose-response effect of the relaxation and quantity of MEBM, but no

Table 2. Demographic information of studies

Authors	**Country**	**Sample**	**Main Outcome**	**Sample Size**	**Maternal Age** Mean (SD)	**Gestational Age (weeks)** Mean (SD)
Feher et al. (1989)	USA	Breastfeeding mothers	Milk volume, fat & calorie content	Control (n=25)	26.8 (6.2)	30.8 (not reported)
				Relaxation (n=30)	24.5 (6.2)	31.5 (not reported)
Keith et al. (2012)	USA	Breastfeeding mothers	Milk volume, fat & calorie content	Treatment as usual (n=43)	27.5 (5.7)	32.5 (5.1)
				Verbal relaxation + music (n=42)	24.6 (5.8)	31.7 (4.0)
				Verbal relaxation + music + image (n=40)	26.3 (6.4)	31.7 (4.9)
				Verbal Relaxation (n=35)	29.1 (6.9)	31.3 (3.8)
Karbandi et al. (2015)	Iran	Mothers	Sleep	Control (n=30)	27.8 (5.5)	Not reported
				Relaxation (n=30)	28.2 (6.7)	Not reported
Fotiou et al. (2016)	Greece	Parents	Stress & Anxiety	Control (n=28)	37.5 (33.0-41.0)*	33.0 (32.0-34.0)*
				Intervention (n=31)	34.5 (30.5-39.5)*	33.0 (31.0-35.0)*

* = Median and interquartile range provided

statistical analysis was provided to identify if this was significant. Keith et al. (2012) did not report the frequency of use of the intervention or any comparisons between the intervention conditions.

Feher et al. (1989) reported that relaxation did not significantly impact on the fat content[1] of MEBM. Keith et al. (2012) noted when verbal relaxation, plus music, plus images were used there appeared to be significantly higher fat content of MEBM produced from day one to day eleven compared to controls.

Maternal Sleep

Karbandi et al. (2015) recruited mothers from an Iranian NNU, when they were 24-72 hours post-partum, with an infant who had a gestational age between 32 and 36 weeks. Mothers who received relaxation attended one 45-minute training session and were given a CD of a PMR practice to use daily. The control group were asked to use deep breathing when necessary. Both groups participated over 8 weeks and sleep quality was self-rated by mothers at baseline, four and eight weeks. Karbandi et al. (2015) reported the reason for pre-term birth, level of income, level of education and delivery mode did not statistically differ between groups. They did not report on the length of stay or when the infant was discharged from the NNU. They also did not report the mean gestational age of infants in the groups.

Following the use of relaxation, mothers rated their sleep quality significantly better at week 4 and 8 compared to controls (Karbandi et al., 2015).

[1] Fat content was explored due to the importance of infant growth and nutritional need while in the NNU. It was questioned whether relaxation could improve the quantity and quality of MEBM (Keith et al., 2012).

Those using relaxation also had significantly improved sleep quality between week four and eight, which was not found within the control group (Karbandi et al., 2015). All significant findings were of a large effect size (Table 3). Mothers' frequency of use of relaxation was not reported.

Parental Stress and Anxiety

Fotiou et al. (2016) recruited parents who had infants less than 37 weeks gestation to either a control or relaxation group. "Parental pairs" were randomised to the same group. Parents in both groups attended five, 90-minute training sessions. In the relaxation group, 20 minutes was dedicated to practicing relaxation. They were also given a relaxation CD and were sent weekly text reminders to complete relaxation. Parents in the control group received information about experiences in the NNU and an information CD. Fotiou et al. (2016) recorded baseline stress 10-15 days post-delivery and measured it again 3 months after discharge. They reported no significant differences between the groups on parental age, infant age, apgar score, total days in the NNU, marital status, level of income and method of birth. They did not report how many "parental pairs" participated.

Fotiou et al. (2016) reported a significant reduction in trait anxiety for parents who had used the relaxation intervention. There was a small to medium effect of relaxation on the reduction of trait anxiety (Table 3). No other significant findings were reported. Both had a relative reduction in stress from baseline to month three. Both groups remained above the clinical cut off score for the Perceived Stress Scale and the State Trait Anxiety Inventory. Fotiou et al. (2016) did not report parents' frequency of use of relaxation.

Table 3. Measures used, reported findings and p values

Measures	Description of Intervention	Findings	*p*=*	*d*=[a]
Milk volume & fat content	**Relaxation:** 20-minute audio relaxation, PMR and GI. **Frequency:** Encouraged to use daily around the time of milk expression **Duration:** 7 days	Mean volume of milk higher in relaxation group: 90.1ml (relaxation) 55.4ml (control).	<0.05	0.64
		Creamatocit of milk no significant difference between the groups.	N/R	-
		The more mothers listened to the tape the higher the quantity of milk.	N/R	-
Milk volume & fat content	**Relaxation**: Mp3 player with 12-minute PMR then GI accompanied by music and/or images of infant depending on intervention condition. **Frequency**: As often as possible when expressing **Duration**: 14 days	All intervention groups produced significantly more milk than treatment as usual participants at day 14.	<0.001	-
		Verbal only vs treatment as usual (at day 14).	<0.01	0.90
		Verbal + music vs treatment as usual (at day 14).	<0.01	1.76
		Verbal + music + image vs treatment as usual (at day 14).	<0.01	2.30
		Verbal, music + image group had a higher fat content for days 1-11 compared to control group.	<0.01 – 0.16	-
		Verbal relaxation group had a higher fat content of milk from days one to six.	<0.001	-
PSQI	**Relaxation:** 30-45-minute training session of PMR Audio CD of PMR, a written guide & self-report checklist to use at home. **Frequency**: Asked to complete once daily. **Duration**: 8 weeks	4 week mean PSQI score lower in relaxation group.	0.024	3.31
		8 week mean PSQI score lower in intervention group.	<0.001	7.50
		Control group: no difference in PSQI between week 4 and week 8.	0.64	-
		Intervention group improved PSQI scores between week 4 and week 8.	<0.001	4.48
PSS, STAI, STAI-1, & STAI-2	**Relaxation:** 5, information courses with 20-minutes of each session for diaphragmatic breathing, GI & PMR **Frequency:** Encouraged to practice twice daily. Text reminders sent weekly **Duration:** 3 months	Both groups demonstrated a reduction in anxiety three months after discharge.	0.186	-
		Intervention group had a significant reduction in trait anxiety compared to control group.	0.02	0.38
		Perceived stress declined in both groups.	0.699	-

Abbreviations: Pittsburgh Sleep Quality Index (PSQI), State-trait Anxiety Inventory (STAI), (State Anxiety STAI-1, trait anxiety STAI-2) Perceived Stress Scale (PSS) Progressive Muscular Relaxation (PMR), Guided Imagery (GI). * *p* values that were not reported indicated by N/R. [(a)] Effect size calculation: Cohen's $d = M_1 - M_2 / \sigma_{pooled}$

Discussion

This review aimed to identify how parents with an infant admitted to the NNU could benefit from the use of a relaxation intervention. It firstly identified that in contrast to research of relaxation outwith the NNU, there are very few randomised control studies exploring the impact of relaxation for parents within the NNU. A systematic review of the use of relaxation to manage symptoms of anxiety in adults identified 19 studies and concluded that PMR and autogenic training reduced anxiety with a medium to large effect size (Manzoni et al., 2008). A review of the use of relaxation by mothers during pregnancy concluded that techniques such as PMR, and guided relaxation consistently improved mothers psychological well-being and lowered their heart rate and blood pressure (Fink et al., 2012). From the four studies identified in the current review, three areas were explored: MEBM, maternal sleep, and parental stress and anxiety levels. Each will be discussed in turn.

Maternal Expressed Breast Milk

Feher et al. (1989) and Keith et al. (2012) identified that relaxation increased the quantity of MEBM produced with a medium to large effect size at day seven (Feher et al., 1989) and day fourteen (Keith et al., 2012). There appeared to be a high risk of performance and detection bias within Feher et al. (1989), due to lack of reported staff blinding and only one measurement of MEBM. As both groups received verbal and written staff support, this could have differed between groups. Other variables were not accounted for, such as the use of breast massage, or frequency of expressing, which could impact on the quantity expressed (Becker, Smith and Cooney, 2016).

In support of Feher et al's. (1989) findings, Keith et al. (2012) collected data over 14 days and also reported that mothers who received relaxation produced significantly higher quantities of MEBM compared to those in the control group. Smaller scale research also supports the findings of Keith et al. (2012) and Feher et al. (1989). Feijs et al. (2013) used biofeedback as a method of relaxation (n=7) in a Dutch NNU. A trend of mothers expressing a greater quantity of milk following one session of relaxation was noted (Feijs et al., 2013). This could be due to variables not accounted for in a small sample, however this is further supported by the physiology of breastfeeding. Oxytocin stimulates the expression of breast milk. Oxytocin production can be inhibited by hormones released when we become stressed. By maintaining a relaxed state, oxytocin production can occur more freely (Lawrence and Lawrence, 2011). Although Feher et al. (1989) and Keith et al. (2012) use the physiological link between stress and milk production as the rationale for exploring if relaxation is an effective intervention for milk expression, neither study employed a measure of stress hormones. Therefore, while there is some evidence that relaxation could support milk expression, Feher et al. (1989) and Keith et al.'s (2012) findings cannot be linked to levels of stress the mothers experienced.

Results published in a poster presentation suggested that mothers who received relaxation had greater self-efficacy in providing MEBM than controls (Hosseini and Hosseini, 2015). It has also been identified that some mothers experience anxiety about their ability to provide enough milk for their infant (Alves et al., 2013) which could impact on their stress levels. It is important for future research to consider how relaxation could support mothers to provide MEBM due to numerous health protective properties the milk contains for their vulnerable infants (Underwood, 2013; Horta and Victora, 2013). Furthermore,

mothers who were able to express milk were able to transition to breastfeeding when their infant's health improved. This provided an opportunity for bonding with their infant which may not have occurred for mothers whose milk dried up (Ikonen et al., 2015).

Maternal Sleep

Mother's scores were above the clinical cut off for the Pittsburgh Sleep Quality Index at baseline and after eight weeks, which indicated that overall sleep quality remained in the "poor" category (Karbandi, et al. 2015). Despite this, mothers' ratings of their sleep quality, with the use of PMR, significantly improved with a large effect size over eight weeks. Caution should be applied in the interpretation of these results based on the information provided in the report.

There appeared to be a high risk of selection bias as mothers were recruited to a condition based on when their infant was admitted to the NNU. Furthermore, there is no data reported on the frequency of relaxation use, or when infants were discharged home. Data collection occurred for 8 weeks and inclusion criteria stipulated that mothers with infants born between 32-36 weeks gestation were eligible. It is possible that some infants could have been discharged home within the study time frame. The stress experienced due to separation from their infant impacted on mothers' sleep (Heidari et al., 2013) and those with their infants at home experienced naturally occurring reductions in sleep disturbance (Filtness et al., 2014). Therefore, if infants went home during the data collection phase, this could have influenced a mother's perception of her sleep quality.

In support of Karbandi et al. (2015) findings, a single group (N=20) repeated measures study in an American NNU reported that relaxation improved mothers' perception of sleep quality (Schaffer et al., 2013). It is likely that the

infants remained in the NNU during this period due to the eligibility criteria. Schaffer et al. (2013) also reported that sleep quality remained within the "poor" category following the use of relaxation.

It is important for researchers and clinicians to continue to develop maternal sleep interventions, as subjective reports of poor sleep quality have been identified as a risk factor for the occurrence of post-natal depression (Bei, Coo and Trinder, 2015). Schaffer et al. (2013) reported that the frequency of using relaxation appeared to impact on its effectiveness of self-reported sleep quality, which could be clinically relevant. This is supported outwith the NNU, with relaxation reported to be more effective the more it was practiced (Manzoni et al., 2008). It would be beneficial for future research to consider when and how often relaxation is used, the potential transitions occurring for families and the impact this could have on sleep quality and mood.

Parental Stress and Anxiety

One study explored the impact of relaxation on stress and anxiety in parents with an infant in the NNU. While all parents recruited reported a reduction in stress they remained within the "high" range of stress and anxiety at the 3 month follow up (Fotiou et al., 2016). This is in contrast to the reported medium to large effect of relaxation reducing levels of anxiety outwith the NNU (Manzoni et al., 2008, Fink et al., 2012). It also differs from Shaw et al.'s (2013) findings, who applied a cognitive behavioural approach, which included one session of relaxation. They noted that both the intervention and control groups reported reduced anxiety but this fell to a sub-clinical level within 5 weeks.

Fotiou et al. (2016) noted a significant reduction in trait anxiety between the relaxation and the control group at 3-months post discharge. This is surprising

as trait anxiety is believed to be more enduring than state anxiety (Julian, 2011). This finding may be due to an increase in trait anxiety at the 3-month point in the control group rather than a significant decrease in the intervention group. This change in ratings may be a reflection of the dynamic stressors of parenthood, due to the constant changes in their infant's presentation and needs over time. It may be that the group who received weekly phone calls to use relaxation had a consistent resource to access which may help to lower trait anxiety (Fotiou et al., 2016). This could result in the perception of anxiety being less pervasive or overwhelming.

It is important for future clinicians and researchers to consider the use of relaxation to help parents manage stress due to the impact it can have on parents' interaction with their infant. As previously mentioned, stress can negatively impact on the hormones that allow mothers to provide MEBM for her infant (Lawrence and Lawrence, 2011). Higher levels of maternal stress within the NNU has indicated a greater likelihood of mothers experiencing depression (Davis et al., 2003) which can result in a poorer quality of interaction with their infant (Korja et al., 2008). For fathers, stress experienced while his infant is in the NNU can result in allowing staff to care more for their infant which can limit opportunities for positive interactions with their infant (Schappin et al., 2013). Further research into the use of relaxation on parental stress and anxiety would be useful. It could be helpful to determine if the effectiveness of relaxation differs between mothers and fathers given suggestions that sources of stress and anxiety while infants are in the NNU may differ (Schappin et al., 2013).

Strengths and Limitations

A strength of this review is that it highlights the need for further high quality research to establish how relaxation can optimally be used for parents with an infant within the NNU. It highlights the need to consider the multiple variables which may impact on parents during this stressful period to determine the true effectiveness of relaxation interventions. This should include consideration of social factors that could impact on stress levels, duration of infant stay within a NNU, and the emotional wellbeing alongside physiological factors (milk expression / sleep). In addition, given that Feher et al. (1989) and Schaffer et al. (2013) reported there could be a dose-response effect to the use of relaxation, future studies should plan to capture this information.

A limitation of this review is that there were very few RCTs to report on and therefore the validity and generalisation of these results is poor. The majority of studies discussed were based in the American health care system which may bias findings. Furthermore, due to the limited data and the different areas explored, no meta-analysis could be completed.

In a time of limited resources health services are looking for interventions which are cost effective for people to use. As different health care systems may provide unique stressors, more research is needed in a wider geographic area. In the UK there is an enhanced focus on early intervention and stepped care approaches for perinatal mental health (Scottish Government, 2016). It could be helpful to identify if relaxation can benefit mothers in the UK where there are low breast feeding rates (Victora et al., 2016).

Conclusions*:*

To conclude, there is some promising data to suggest that relaxation could be beneficial for MEBM quantity and mothers perception of sleep quality, but

there was limited data to suggest relaxation could be useful for parental stress and anxiety levels. Given the effectiveness of relaxation out with the NNU environment (Manzoni et al., 2008; Fink et al., 2012) there needs to be further high quality research conducted to determine the potential benefits of relaxation for parents during this stressful time. Future research needs to consider multiple variables which may impact on parents' functioning and mood during this time. Furthermore, potential differences between the effectiveness of relaxation for mothers and fathers should be explored to help determine the potential benefits and limitations of this approach within a stepped-care model within NNUs.

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Chapter 2: The Application of Relaxation for Mothers Expressing Breast Milk for Their Infant in the Neonatal Unit: A Feasibility Study

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Word Count: 7567

Prepared in accordance with the Journal of Reproductive and Infant Psychology guidelines for submission

Disclosure Statement: The author reports no conflicts of interest.

Plain English Summary:

Objective: Is it possible to recruit mothers with infants in a Neonatal Unit to engage in 14 days of data collection and use of relaxation?

Background: It is recommended that infants should receive only breast milk from birth to six months due to its health protective properties. Due to ill health some infants may be admitted to a Neonatal Unit and are not able to feed from the breast, so mothers express breast milk. This can be difficult for mothers with infants in a Neonatal Unit due to separation from baby, feeling obliged to provide milk and worrying that they will not provide enough milk. Mothers who want to provide milk, but who are unable to, are at a higher risk for developing depression. Mothers who used relaxation in Neonatal Units in America, produced more breast milk than mothers who did not. It is believed that mothers who are stressed produce a hormone which reduces the production of breast milk. As far as the researcher is aware there have been no research studies into the use of relaxation in neonatal units in the UK, where breastfeeding rates are low. Therefore, it needs to be determined if it is feasible to recruit mothers to a research trial, before researching if the intervention is effective.

Method: Mothers who were fluent in English and providing expressed milk for infants admitted to neonatal units in Glasgow and Ayrshire, were invited to participate. Mothers who chose not to participate had their reasons recorded.

Mothers were randomly allocated to treatment as usual, or a relaxation group. The relaxation group received the standard treatment, plus a recording of a 15-minute relaxation practice. Mothers had access to the recording in the unit and were given a CD copy. A daily text reminder was sent to mothers to use relaxation. Mothers answered a questionnaire about their use of relaxation after 14 days.

Mothers emotional wellbeing was measured by the Edinburgh Postnatal Depression Scale and the Parental Stressor Scale: Neonatal Intensive Care Unit. Mothers recorded how much and how often they expressed milk.

Results: Over 6 months, 192 mothers met the criteria to participate. Fifteen agreed to take part (8 received relaxation, 7 received usual treatment). The most common reason mothers reported for not participating was not having enough time. Due to the small sample no statistics were performed on the data related to milk or emotional wellbeing. One mother from each group dropped out.

100% (n=7) of mothers who used relaxation reported they would recommend it to other mothers. Only 28% (n=2) believed the practice helped them feed their baby. Mothers reported that the intervention could be enhanced by improving the use of technology such as developing an app.

Conclusions: Mothers reported timing to be the greatest barrier to participation and engagement with relaxation. Therefore, suggestions are made regarding how future research can make sharing information about participation more accessible. The way mothers' emotional wellbeing and milk production is recorded is discussed in relation to accessibility and sensitivity. It is recommended that future research is conducted to determine if there is an effect of relaxation on stress and milk quantity for mothers with infants in the neonatal unit in the UK.

Scientific Abstract:

Objective: Is it feasible to recruit mothers with infants in a neonatal unit (NNU) to engage in 14 days of data collection and use of relaxation?

Background: In a NNU mothers may express breast milk for their infant. The NNU has specific stressors, which may impact on emotional wellbeing and ability to provide expressed milk. Relaxation significantly increased the quantity of expressed milk for American mothers. This has not been replicated in the UK, where rates of breastfeeding are low, therefore a feasibility study is needed.

Method: A random allocation (treatment as usual vs relaxation), repeated measures design was used. Mothers providing expressed milk were eligible to participate. If mothers chose not to participate their reasons were recorded. Mothers accessed relaxation through a MP3 or personal CD. Mothers completed expression logs (14 days), Edinburgh Postnatal Depression Scale, and Parental Stressor Scale: Neonatal Intensive Care Unit (day 1,7 and 14). Mothers answered questions about their use of relaxation after 14 days.

Results: 192 mothers were eligible to participate. Fifteen mothers were recruited (Relaxation n=8, TAU n=7) in 6 months. One dropped out from each group. Not having enough time was the most commonly reported reason for not participating. 100% (n=7) of mothers who used relaxation would recommend it to other mothers. Only 28% (n=2) believed the practice helped them feed their infant. Mothers reported the intervention could be improved by making better use of technology. Due to a small sample no inferential statistics could be completed on milk or emotional wellbeing data.

Conclusions: Due to the importance mothers placed on their time, the accessibility of research information and relaxation are discussed. Suggestions of how to reduce barriers in future research, which could determine if relaxation supports mothers' emotional wellbeing and milk production, are made.

Keywords: Relaxation, Mother, Expressing, Well-being, Neonatal Unit.

Introduction

The World Health Organisation recommends that all infants should be fed exclusively breast milk from birth to six months (WHO, 2007). Some infants are unable to feed from the breast due to ill health. Depending on an infant's severity of illness, they may be admitted to the Special Care Baby Unit (SCBU) or Neonatal Intensive Care Unit (NICU) which are within the Neonatal Unit (NNU). During this time, mothers can express their breast milk for their infant. Mothers can express milk from the breast by hand or use a machine. It has been suggested that mothers who express milk may not experience the same opportunity for bonding which may occur through the closeness of an infant feeding directly from the breast (Thorley, 2011). This maternal expressed breast milk (MEBM) is valuable for infants in the NNU because it contains short and long term health protective properties (Horta and Victora, 2013; Underwood, 2013) and is a predictor of infant survival in low birth weight infants (Boo, Puah and Lye, 2000).

High income countries have the lowest breastfeeding prevalence globally (Victora et al., 2016). In the UK, 34% were receiving breast milk at 6 months old (McAndrew et al., 2012). Infants in the UK admitted to the NNU were more likely to be given breast milk for up to one week compared to healthy counterparts (McAndrew et al., 2012). At the point of discharge from the NNU, rates of infants receiving breast milk ranged from 43% to 85% across the UK (Royal College of Paediatrics and Child Health, 2016).

Research around the world has identified that the choice to initiate and sustain breastfeeding is determined by a complex relationship between demographic, physical, social and psychological factors (Ajetunmobi et al., 2014; Thulier and Mercer, 2009). It was identified that for mothers with infants in the NNU there were additional stressors that impacted on the decision to provide

breast milk. These were the task being perceived as a “duty” or the only thing a mother can do to care for her infant at that time (Flacking et al., 2006; Sweet, 2008).

During this time mothers also go through a process of adjusting to becoming a mother in the NNU environment (Fenwick, Barclay and Schmied, 2008). This can involve striving to provide physical care for their infant in a medical environment. It is believed this coincides with mothers fluctuating between feeling connected to their infant and struggling emotionally (Fenwick et al., 2008). Qualitative studies identified factors specific to the NNU that can negatively impact on maternal feeding experiences. These are; worries of inadequate milk supply, strangers and staff nearby, a noisy and stressful environment and adjusting to the early arrival of infant (Alves et al., 2013; Flacking et al., 2012; Nyqvist and Engvall, 2009). Therefore, it may be that targeted interventions to reduce stress may improve maternal feeding experiences.

The UNICEF UK Baby Friendly Initiative (Entwistle, 2013), which is a set of standards that apply to maternity, neonatal and heath visiting services, is the main intervention to promote breastfeeding for mothers in the UK**.** A Cochrane review identified that warm breasts, breast massage, expressing in the hour after birth and pumping four or more times per day had a positive effect on the quantity of MEBM (Becker, Smith and Cooney, 2016). A systematic review of breastfeeding interventions specific to the NNU, found strong evidence that Kangaroo Care (a skin to skin contact programme), and peer support were effective interventions (Renfrew et al., 2009). These activities are encouraged within NNUs.

Two American randomised control trials reported that relaxation had a significantly positive effect on the quantity of MEBM while infants were in the

NNU (Feher et al., 1989; Keith, Weaver and Vogel, 2012). Relaxation is frequently applied in psychological interventions to help regulate emotions. Relaxation may be helpful for mothers expressing milk, due to the hormones associated with stress and milk production. The hormone oxytocin stimulates the let-down of breast milk, however, hormones which are released to reduce stress (opiate and β-endorphin) inhibit oxytocin production (Lawrence and Lawrence, 2011). Neither Feher et al. (1989) nor Keith et al. (2012) measured stress alongside the use of relaxation. When psychological distress was measured through a visual analogue scale, it was found that mothers of preterm infants experienced greater psychological distress than mothers of healthy infants, but this was not associated with milk supply at 6 weeks postpartum (Hill et al., 2005). It is questioned whether this finding would be upheld if a standardised mood measure was employed.

Finally, research of interventions to date have negated to explore maternal goals for feeding their infant (Becker et al., 2016). Mothers who had planned to breastfeed but were unable to, were at higher risk of post-natal depression (PND) compared to mothers with alternative feeding expectations (O'Donnell, 2015; Borra, Iacovou and Sevilla, 2015). This may be understood through Beck's psychological model of depression, where a depressive episode can be triggered by loss (Beck and Alford, 2009). The loss of the ability to achieve their feeding goal, if a mother's milk dries up, and associated feelings of failure (Borra et al., 2015), may trigger depression. In an Iranian NNU, mothers who used relaxation reported greater levels of self-efficacy for feeding their infant (Hosseini and Hosseini, 2015). Due to the potential that a relaxation intervention could increase milk quantity and self-efficacy, a secondary gain could be that it helps mothers maintain their feeding goals which could be protective against PND.

Currently there are no identified UK studies which explore the use of relaxation with mothers with infants in the NNU. Infants in the NNU are more vulnerable to health complications which MEBM can provide protection against. There may be specific factors in the NNU that make it difficult for mothers to express milk. Therefore, it is essential to understand how mothers could be supported to provide breast milk for their infants by conducting more research. Due to the low prevalence of breastfeeding within the West of Scotland (ISD Scotland, 2016) it first needs to be established if it is feasible to recruit mothers within the NNU to use relaxation. Knowing if mothers are willing to engage in the consistent use of relaxation, and if the intervention improves physiological processes, and psychological wellbeing would be beneficial for planning future research.

Aims

This project aims to determine if it is feasible to recruit and engage mothers who have an infant in the NNU to use relaxation and complete measures of mood and milk expressed over 14 days.

Research Questions

1) Is it feasible to recruit mothers who are expressing breast milk for 14 days?
2) Do mothers engage with the use of a relaxation intervention?
3) Does relaxation impact on milk quantity, frequency of milk expression, emotional wellbeing and maintenance of maternal feeding goals?

Methods

Design

A mixed method, random allocation, repeated measures design was used. Mothers were randomly assigned to treatment as usual, or relaxation by block allocation. Mothers opened a sealed envelope, which informed them of their allocation. The researcher did not remain blind once the participant revealed their allocation, due to resource and practical limitations.

To assess the feasibility of using relaxation, qualitative data was recorded when mothers volunteered reasons for why they had chosen not to participate. Quantitative and qualitative data was collected for mothers who were allocated to the relaxation arm. A descriptive analysis of quantitative data is provided alongside a manifest content analysis (Bengtsson, 2016) of qualitative responses. The manifest content analysis followed the steps of decontextualisation, recontextualisation, categorisation and compilation. (Bengtsson, 2016). The content was reviewed by a second analysist and themes were agreed upon. Pseudonyms are provided for the analysis.

Treatment as usual **(TAU)–** Mothers received standard care, which included access to a breastfeeding support advisor, and information leaflets which provide instruction for expressing.

Relaxation intervention – In addition to the above, mothers received a 15-minute progressive muscular and guided imagery relaxation exercise. This was an adaptation of relaxation for breastfeeding with permission granted by the author for use in the study (McGruder-Johnson, 2007). It was recorded with a British voice and comments regarding infant presentation were removed to specifically

account for how an infant may present in the NNU. Mothers could access the practice via a MP3 player in the NNU and a personal CD copy. They were sent a daily text reminder to use relaxation. Mothers completed a questionnaire about their use of relaxation after 14 days.

Participants

Participants were mothers (over 18 years old) of infants admitted to the NNU in the Royal Hospital for Children, Glasgow between November and April 2017 and Ayrshire Maternity Unit between February and April 2017. The two units had 50 and 24 beds respectively. Mothers who were fluent in English and providing MEBM were invited to participate. Mothers were not invited to participate if they were infected with HIV or tuberculosis, had medical treatment or substance-use which negatively impacted on MEBM, or where there was a high chance of infant death (determined by the medical team).

As this was a feasibility study, the main aim was to see if mothers could be recruited. A-priori power analysis was completed through GPower (Erdfelder, Faul, Lang and Buchner, 2007) to estimate a reasonable sample size target. To detect a medium effect size (f =0.45) as reported in Keith et al. (2012), with power at 0.80, alpha at .05, using 14 measures (mean milk per day) with a moderate correlation between measures ($r_{s\backslash}$=0.75) and using a repeated measures ANOVA, a total sample size of 34 would be needed. To accommodate for a potential 25%, dropout rate as reported in Feher et al. (1989) a total sample size of 44 was the recruitment target. See Appendix 2.1 for explanation of a change in the calculation process.

Ethical Approval

Initial and subsequent amendments for changes to the recruitment strategy (Appendix 2.2) were granted ethical approval by West of Scotland Research Committee 5 (Appendix 2.4). The study was approved by R&D departments in NHS Greater Glasgow and Clyde (reference: GN16MH457) and NHS Ayrshire and Arran (reference: 2017AA009A&A).

Measures

Maternal age, gestational age, birth weight, apgar score at birth, experience of breastfeeding and expressing, number of previous children, postcode and factors related to visiting their infant were collected through a questionnaire (Appendix 2.5) and by reviewing the infant's medical file (Appendix 2.6).

Edinburgh Postnatal Depression Scale (EPDS) (Cox, Holden & Sagovsky, 1987) – The EPDS is a 10-item self-report postnatal depression screen. It asks mothers about their feelings over the past 7 days. Scores range from 0 to 30 with a total score over 10 indicating the likelihood that a mother is experiencing significant distress (Cox et al., 1987). The EPDS is a reliable measure with an alpha coefficient of 0.87 (Cox et al., 1987) and is sensitive for use within the first week post-partum (Jardri et al., 2006).

Parental Stressor Scale: Neonatal Intensive Care Unit (PSS: NICU) (Miles, Funk and Carlson, 1993)- The PSS: NICU is a 26-item self-report scale investigating parental perception of stress. Parents rate on a 5 point Likert scale (1= "not at all stressful" to 5 = "extremely stressful") the degree of distress experienced in relation to each item. A mean stress score is then calculated for

each scale. The overall mean parental stress has good reliability with α= 0.89 (Miles et al., 1993). There are two subscales that account for stress related to infant appearance (19 items) and parental role (7 items). The two subscales have good reliability with α= 0.92 (Miles et al., 2007).

Maternal measurement of feeding goals (Hoban et al., 2015) – Mothers were asked the type of food and method of feeding they wanted for their infant (Appendix 2.7). Mothers were asked what their pre-delivery, post-delivery, end of study, and future feeding goals were for their infant.

Mothers' experience of the intervention – Following participation, mothers who received relaxation completed a questionnaire about their experience (Appendix 2.8). The questionnaire explored feasibility concepts such acceptability, demand, implementation, practicality, and integration (Bowen et al., 2009).

Milk quantity – Mothers completed the standard expressing log which asked them to record quantity of milk each time they expressed and if they engaged in Kangaroo Care (Appendix 2.9).

Procedure:

Mothers of babies admitted to the NNU were approached by clinical psychologists, nursing staff or the researcher with participant information sheets (Appendix 2.10). Mothers who wanted to participate gave signed consent (Appendix 2.11) and completed demographic and baseline mood questionnaires (EPDS and PSS: NICU). Mothers opened an envelope to reveal which arm they had been allocated to. All mothers completed the expressing log each time they expressed for 14 days. The EPDS and the PSS: NICU were repeated on day 7 and

14. All mothers completed the feeding goals questionnaire on day 14. Mothers in the relaxation arm completed the experience of the intervention questionnaire on day 14. All mothers were contacted at least 3 months after their participation and asked if they were still providing breastmilk for their infant.

Results

Question 1: Is it feasible to recruit mothers who are expressing breast milk for 14 days?

The study did not achieve the target sample of 44 participants. From 192 mothers who were confirmed to be expressing milk, 15 were recruited (Figure 1). Sixty-five mothers (34%) had infants in the SCBU and 127 (66%) had infants in the NICU when they received the participant information. The median age of infants was 7 days (IQR 3-16) when mothers were given the information about the study.

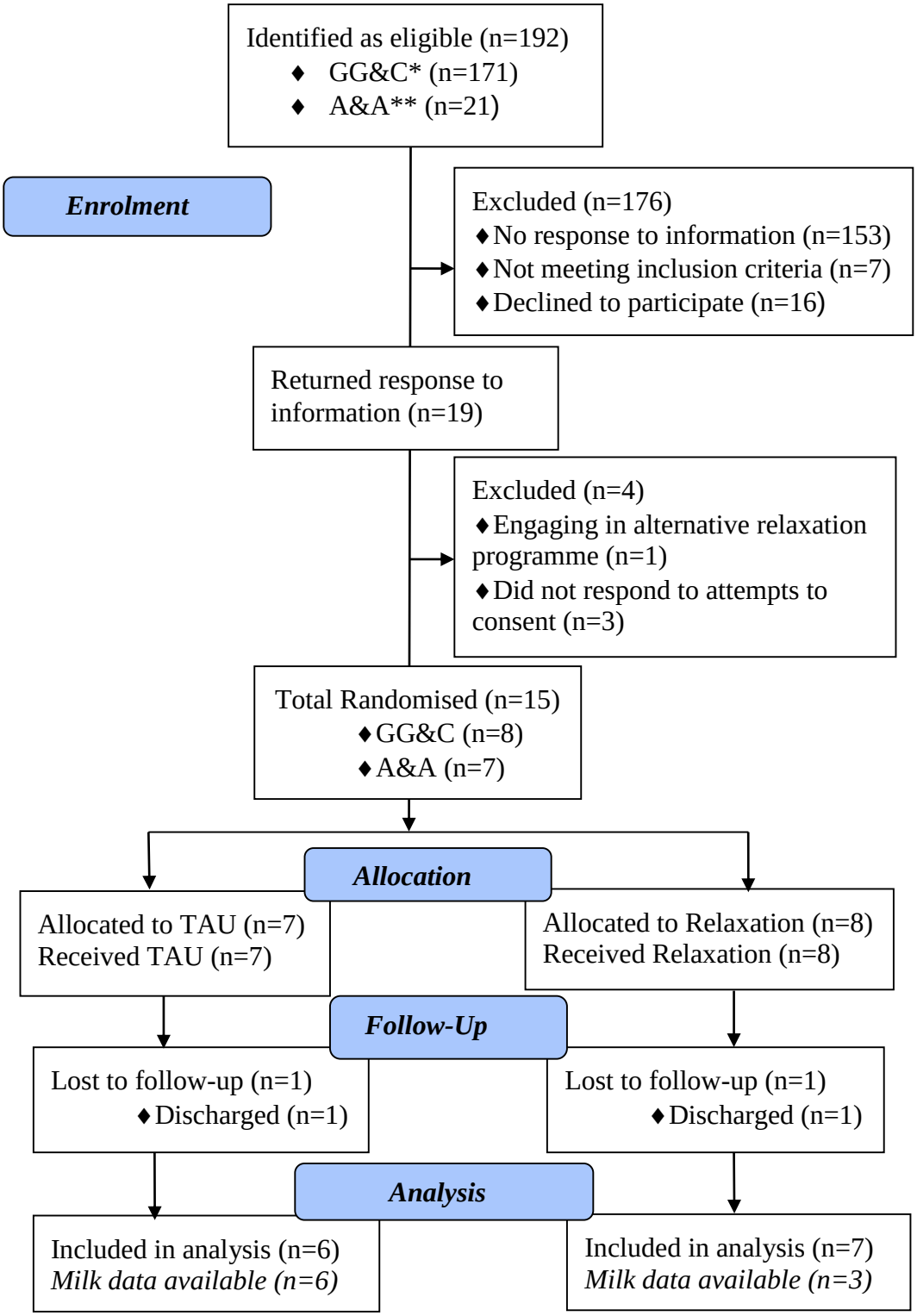

Figure 1. CONSORT Flow Diagram (Schulz, Altman and Moher, 2010)

*Greater Glasgow & Clyde (GG&C) recruitment was November 2016-April 2017,

**Ayrshire and Arran (A&A) Recruitment was February 2017-April 2017

Nineteen mothers replied to the participant information. Four did not go on to participate. One had started a relaxation programme between the time of submitting her note of interest and meeting the researcher. Three did not respond to researcher phone calls or attempts to meet on the ward before the infant was discharged.

Sixteen mothers volunteered reasons why they did not want to take part (Appendix 2.12). Through content analysis four main themes were identified;

1. Time (n=9): Mothers reported that they did not have time to complete the tasks of the project.

> "I don't have enough time to do the study" (Mary)

The theme of time, had a subsection of mothers (n=3) expressing a sense of having "too many other demands" on them at this time.

> "…I don't have time to do that with everything else you have to do when expressing" (Natasha)

2. Transition (n=4): Mothers who had infants whose health was improving, such as moving from NICU to SCBU were focussing on going home.

> "I'm thinking about going home now" (Angela)

3. Lack of need (n=4): Mothers reported that they did not have difficulties expressing milk and therefore no intervention was necessary.

> "I'm not struggling to get milk and there's too many other things going on in my head just now" (Francesca)

Within this theme some mothers were applying techniques from previous interventions. A subsection of lack of need was created for mothers (n=2) who were “applying other techniques” to support them.

> "I used hypnobirthing and I’m still applying those techniques. I’m not struggling so will decline". (Heather)

4. Technology (n=1): one mother reported she did not have a CD player.

The researcher spoke with mothers (n=27) to discuss participation. They reported they received a lot of written information and had not seen the participant information sheet by the cot. All mothers were willing to discuss the study and receive another copy of the information. All mothers who agreed to take part in the study had a conversation with the main researcher, or NNU staff.

Fifteen mothers were recruited and demographic information is presented in Table 1. Mothers had a mean age of 32.20 years (SD=6.88). Infant gestational age ranged from 28-42 weeks (*M*= 32.87 weeks, *SD*=4.24). Seven mothers (47%) who agreed to participate fell into the “most deprived” quintile of socio-economic status.

Ten mothers (66%) had other children, and six (40%) had previous experience of breastfeeding. The number of days expressing prior to giving consent varied, the median was 16 (IQR= 7-26). Eleven mothers (73.3%) reported that they were “sometimes” able to express for the recommended 8 times per day.

Table 1. Demographic information with means (standard deviations) of mothers recruited

		Relaxation (n=8)	**TAU** (n=7)
Maternal age (years)		30.75 (6.88)	33.86 (6.41)
Gestational age (weeks)		32.87 (2.94)	32.86 (5.64)
Birth weight (kg)		1.79 (0.76)	1.79 (0.93)
In Intensive Care when recruited		4 (50.0%)	6 (85.7%)
Apgar score at birth		6 (4)	6 (3)
Multiple births (e.g. twins)		2 (25.0%)	2 (28.6%)
Number that have other children		5 (62.5%)	5 (71.4%)
Number of other children		1 (2)	1 (1)
Previous breastfeeding experience		2 (25.0%)	4 (57.1%)
Number of days expressing		15 (IQR 9.5-19.5)	22 (IQR 4-57)
Socio-economic status	Quintile 1 (most deprived)	4 (50.0%)	3 (42.9%)
	Quintile 2	0	1 (14.3%)
	Quintile 3	3 (37.5%)	2 (28.6%)
	Quintile 4	0 (0%)	1 (14.3%)
	Quintile 5 (least deprived)	1 (12.5%)	0
Distance travelled to hospital	Staying at the hospital	0	1 (14.3%)
	5 miles	4 (50.0%)	3 (42.9%)
	6-10 miles	2 (25.0%)	1 (14.3%)
	11-15 miles	2 (25.0%)	0
	16+ miles	0	2 (28.6%)
Perceived difficulty of travelling	No need to travel	0	1 (14.3)
	No difficulty	3 (37.5%)	5 (62.5%)
	Some difficulty	5 (71.4%)	1 (14.3%)
	Many difficulties	0	0
Ability to express 8-10 times per day	Never	1 (12.5%)	2 (28.6%)
	Sometimes	6 (75.0%)	5 (71.4%)
	Every day	1 (12.5%)	0

Question 2: Do mothers engage with the use of a relaxation intervention?

Seven mothers provided feedback on the use of the intervention, one mother did not because the infant was discharged. Six mothers provided written responses to the open questions about how the intervention could be improved and any additional comments they had (Appendix 2.13).

Across the 14 days, 28.6 % (n=2) of mothers used relaxation 0-4 times, 57.1% (n=4) used it 5-9 times, and 14.3% (n=1) used it 10 times or more.

All mothers reported they would recommend the use of relaxation to other mothers who wish to express breast milk (Table 2). Five mothers (71%) agreed or strongly agreed that they felt calmer after the relaxation practice. Six mothers (86%) found the practice easy to use. Six mothers (86%) agreed or strongly agreed, that the text reminder had been helpful. Four mothers (57%) neither agreed nor disagreed that the relaxation helped them to feed their infant. Four mothers (57%) reported to believe the practice did not help them maintain their feeding goals. There was split opinion on the ease of fitting the relaxation practice into the day with 3 mothers agreeing (42.9%) and 3 mothers disagreeing (42.9%) with this item.

Table 2. Number of mothers and level of agreement with the relaxation feasibility qualities

Intervention Qualities	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
I felt calmer after I had used the relaxation practice	0	0	2	**4**	1
I found the relaxation practice easy to use	0	0	1	**4**	2
I found receiving text reminders to use the relaxation practice helpful	0	1	0	2	**4**
I believe completing relaxation helped me to feed my baby	0	1	**4**	1	1
I found it easy to fit the relaxation practice into my daily routine	1	2	1	2	1
I believe the relaxation practice helped me maintain my feeding goals for my baby	0	**4**	0	2	1
I would recommend the use of relaxation to other mothers who wish to express breast milk	0	0	0	**5**	2

Mothers' responses to questions asking what could be improved with the intervention and if they had any other comments were grouped into four themes:

1. Technology (n=3): Mothers requested that the relaxation intervention be made more accessible by having it in MP3 format so it could be used on phones or tablets:

   "Perhaps an MP3 version that could be downloaded onto a phone" (Naïve)

2. Time (n=2): Mothers commented on the difficulty of completing the practice with other demands for their time.

   "I struggled to fit the relaxation into daily feeding routines as well as juggling travelling/attending to baby's cares" (Sarah)

3. Variation (n=2): Mothers suggested adapting the practice by increasing the choice in practices or making the practice longer.

   "if music was on longer felt that the lesson wasn't long enough" (Tracy)

4. Positive regard (n=2): Two mothers left positive comments about the use of relaxation.

   "for the time I got to use the practice it was good" (Fiona)

Question 3: Does relaxation impact on milk quantity, frequency of milk expression, emotional wellbeing and maintenance of maternal feeding goals?

Four mothers (30%) did not return mood questionnaires for the 7-day time point for various reasons (e.g. infant moving between hospitals or wards, and taking questionnaires home and forgetting to bring them back). Therefore, the analysis explored data from day 1 and day 14. Four participants in the relaxation group did

not have milk data included in the analysis. Three milk logs were not returned, (one was misplaced and two mothers forgot to bring them to the hospital before they were discharged home) and one log was inconsistently completed. The variable of Kangaroo Care is not reported on as it was unreliably completed. Five mothers in TAU and four mothers in the relaxation group recorded when they completed Kangaroo Care, but did not record when they did not complete it. As assumptions cannot be made about why it was not recorded the data was deemed to be invalid.

Milk: As indicated in Figure 2 the relaxation group had a higher baseline milk quantity. While the TAU group appear to have a relatively stable amount of milk produced over time, the relaxation group had greater variability in the amount of MEBM over 14 days. There was little observed difference between the number of times the TAU group (*M*=5.50, *SD*=.99) and the relaxation group (*M*=5.23, *SD*=.12) expressed milk daily.

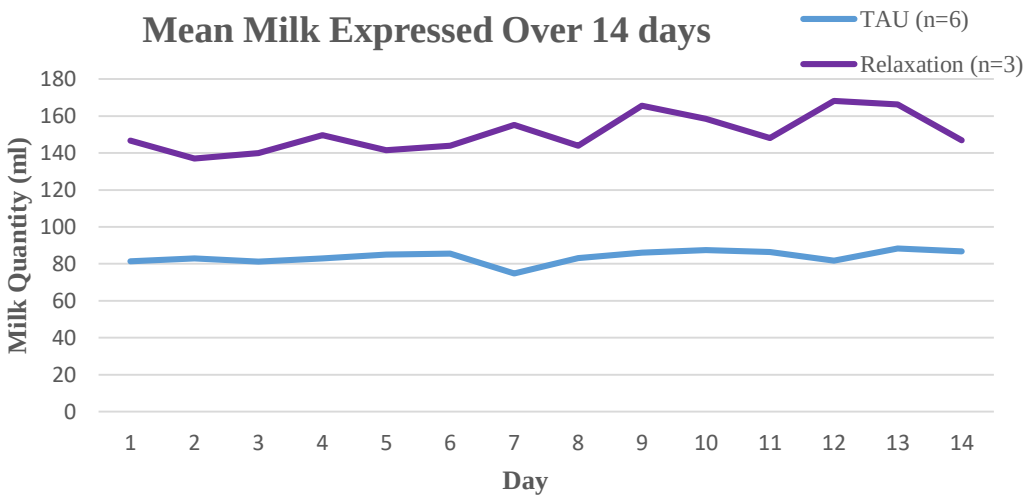

Figure 2. Mean amount of milk produced by the control and relaxation group over 14 days

Emotional Wellbeing: The TAU group had a mean EPDS score which indicated that mothers were likely to be experiencing distress on day 1 (Figure 3). At day 14 the mean score was within the normal range. While the TAU group ratings of stress remained in the same category over time (Figure 4), the relaxation group dropped to the lower category for ratings of overall and role stress. The overall stress mean reduced from "a little stressful" (M=2.03, SD=0.91) to "not at all stressful" (M=1.36, SD=0.14). Role stress reduced from "moderately stressful" (M=3.18, SD=0.32) to "not at all stressful" (M=1.61, SD=0.67).

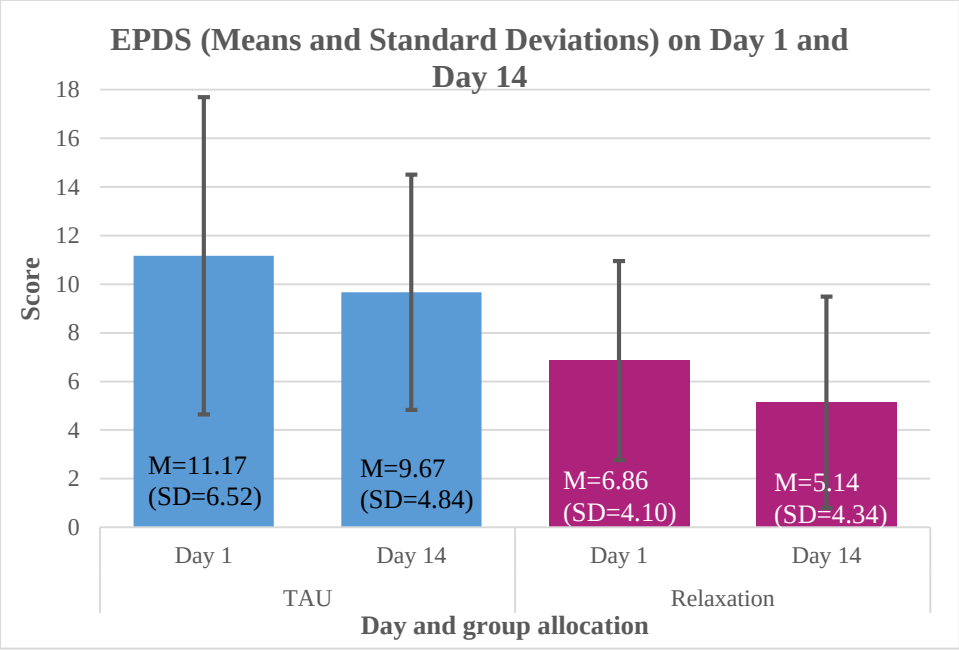

Figure 3. Graph depicting EPDS scores on day 1 and day 14 for TAU and relaxation groups

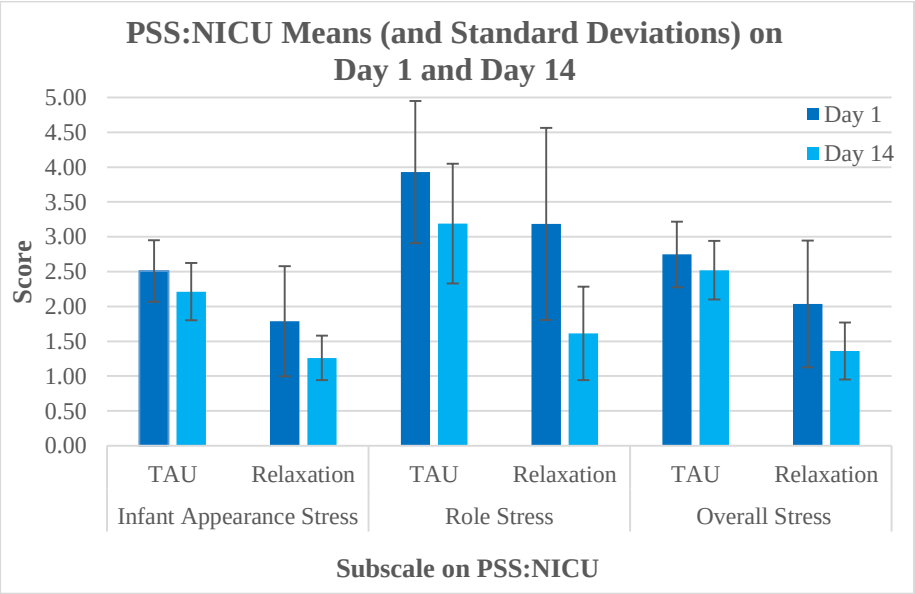

Figure 4. Graph depicting PSS: NICU scores on day 1 and day 14 for TAU and relaxation groups.

Feeding goals: Appendix 2.14 shows the complete distribution of mothers' preferred methods and source of feeding their infants. Data is presented on mothers' preferred source of milk for their infant (Figure 5).

Mothers feeding goals changed over time. Five mothers (83.3%) who received TAU and five mothers (71.4%) who received relaxation wanted to provide exclusively breast milk for their infant before they were born. On day 1 of the study none of the mothers who received TAU and one (14.3%) who received relaxation hoped to provide exclusively breast milk for their infants. By the end of the study six mothers (100%) who received TAU and one (14.3%) who received relaxation hoped in the future their infant would be fed exclusively breast milk.

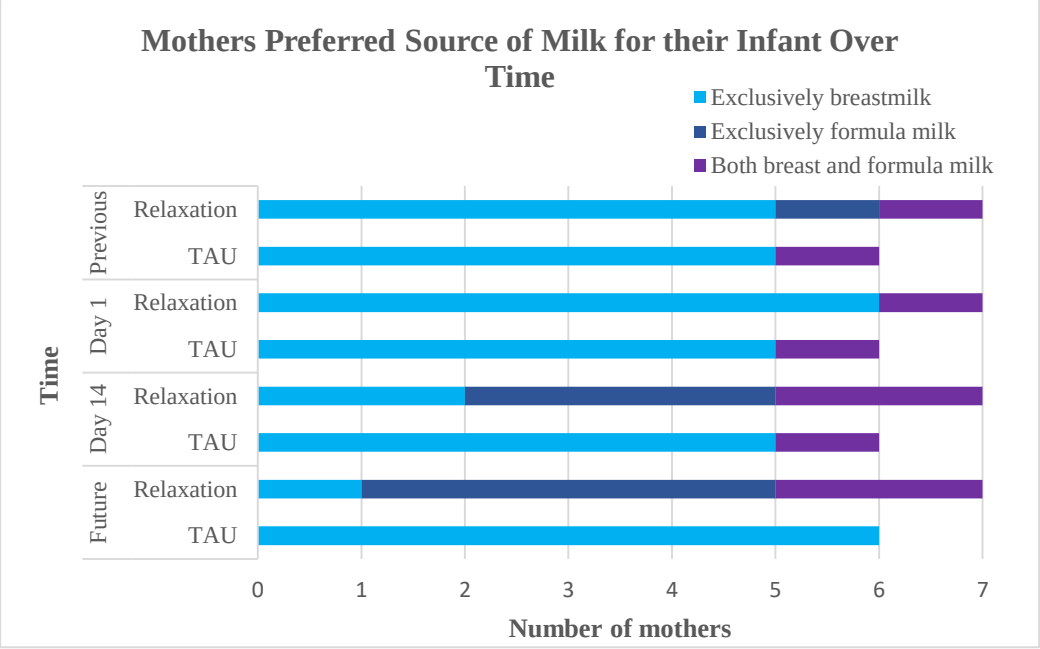

Figure 5. Mothers' preferred source of milk for their infant over time

Three months following the intervention, five of the mothers were unable to be contacted, (n=3 from the relaxation group, n=2 from the TAU group). Of those who could be contacted three of the TAU group and two of the relaxation group had provided breast milk for their infant at three months old.

Discussion

The study aimed to determine if it is feasible to recruit and engage mothers whose infants were in NNU to use relaxation and complete measures of mood and milk expressed over 14 days.

Recruitment

Of the eligible 192 mothers within the NNU only 8% were recruited over 6 months, therefore, the target sample size of 44 participants was not achieved. Neither Feher et al. (1989) nor Keith et al. (2012) reported how long they recruited mothers for, however, two similar studies which recruited parents within

the NNU reported higher recruitment. A study into relaxation and sleep recruited 20 mothers in 5 months (Schaffer et al., 2013) and one into relaxation and stress recruited 59 parents over 15 months (Fotiou et al., 2016).

One of the most common reasons mothers gave for not wanting to take part in the research was not having enough time. This is unsurprising as they are likely to be developing their role (Fenwick et al., 2008) in a stressful environment (Nyqvist and Engvall, 2009) where they have additional demands on their time. It is postulated that if mothers are given information at a time when they may be "just surviving", as suggested by Fenwick et al.'s (2008) developmental model, then they may be more likely to say no. Mothers who agreed to take part did so after they had been in the NNU for a couple of weeks. It may be that at this time they were in the phase that is characterised by information seeking, learning how to physically care for their infant and gathering support (Fenwick et al., 2008). Given the need to quickly establish feeding when the infant arrives, it may be that mothers would benefit from learning relaxation techniques at an earlier stage, such as during pregnancy where there are less demands on mothers (Fink et al., 2012).

Initial observations suggested that written information that was left by the cot for mothers was not seen or read. Mothers reported that they received a lot of written information in the NNU. Furthermore, due to time constraints and staff shift patterns, numbers and capacity it was difficult to ascertain whether NNU staff had spoken to mothers about the research and how mothers responded. The smaller NNU in Ayrshire had a higher percentage of eligible mothers recruited (Figure 1). It is speculated if this was due to greater continuity of care of staff within the NNU. The need for service improvements in providing continuity of care to promote effective communication has been recognised by maternity

services (National Maternity Review, 2016). Additionally, UK research identified that parents feel the lack of privacy inhibits discussions with staff, they are limited in the amount of questions they can ask staff and they do not have a particular staff member to talk to (Reid et al., 2007). Working in the smaller environment in Ayrshire may have meant that nurses appeared more familiar to mothers and could approach at times when there appeared to be less demands on mothers.

The recruitment strategy is important to note because in order to develop the highest standards of care for mothers and infants in the NNU, future clinical research is necessary. There is careful consideration from ethics review panels that helps to ensure that the ethical principle of providing informed consent without coercion is applied by professionals who approach potential participants (Slowther, Boynton and Shaw, 2006). However, within the NNU it was possible that there was a risk of coercion from nursing staff and the researcher. This is because the nurses have an influence on infant care and the researcher had an interest in the progress of the research The lead researcher had the greatest capacity to approach mothers, and had no impact on the provision of care for the mother or infant but was initially unable to approach mothers due to the perceived risk of coercion. It may be that future research needs to consider the environment and who has the best capacity and training to discuss future research with mothers.

Engagement

Of the mothers who were recruited, there was good retention in the study to day 14, however, there were several cases of data not being returned on day 7. Mothers who received relaxation appear to have engaged well with the concept of its use. They would recommend it to other mothers expressing milk, and felt

calmer following the practice. Mothers reported a split opinion about how easy it was to fit the practice into their daily routine. While there is a much smaller sample in the present study, mothers' engagement with the relaxation was less frequent compared to rates reported by Feher et al. (1989). As mothers agreed that the practice was easy to use, it is wondered if the presentation of the practice influenced how easy it was for mothers to fit it into their day. Mothers commented that they believe the intervention could be improved by having access to the relaxation on a mobile phone or tablet. If relaxation was more accessible it could appear less time consuming and therefore easier to complete.

Mothers reported that they did not link the use of relaxation to their ability to provide milk for their infant. It is believed that relaxation could help with milk production, because it can reduce stress which is believed to inhibit the let-down of milk (Lawrence and Lawrence, 2011). If mothers do not associate relaxation with milk production this may impact on mothers' motivation to engage with the intervention. There may be no positive reinforcement to use relaxation when they have competing demands for their time. This may further suggest that engaging in relaxation and understanding the benefits at an earlier stage could be more beneficial for mothers.

Outcomes

Although no inferential statistical analysis could be completed due the sample size, there were useful findings in relation to the feasibility of the measures used. It was noted that mothers baseline mean scores on the PSS: NICU were similar to those reported by a previous UK sample of 257 parents (Franck et al., 2005) suggesting that typical levels of stress were experienced by the current sample.

Mothers who received TAU had baseline mean scores on the EPDS that indicated significant distress (Cox et al., 1987) and between "a little" and "moderate" stress means on the PSS: NICU. It is speculated this may be because a higher proportion of mothers in the TAU group had an infant in intensive care. Infant severity of illness was reported to impact on parental distress within the NNU for UK parents (Franck et al., 2005). This may also account for mothers in the relaxation group's apparent reduction in role stress. If they had less severely unwell infants, it is likely that they were able to provide more hands on care for their infant and therefore experience less stress related to their role. Many variables were accounted for in the current study due to the complex relationships of factors that can impact on maternal feeding experience (Alves et al., 2013; Ajetunmobi et al., 2014; Thulier and Mercer, 2009). As UK services strive to develop stepped care approaches (Scottish Government, 2016) it may be that future research needs to consider if the intervention is effective alongside the infant's severity of illness.

It is acknowledged that there appeared to be difficulties with the measures employed for this study. Mothers who completed the milk log reported the log was helpful to note their progress. There was, however, a low return rate of milk data which suggested that there was some difficulty completing or bringing the log to the NNU. Given the importance of MEBM for these vulnerable infants (Underwood, 2013), it could be helpful for NNUs to complete a service evaluation to determine mothers' engagement with the standard milk log and how mothers are acknowledging their progress of expressing milk.

Furthermore, it was highlighted by two mothers that the wording of the question "I have been anxious or worried for no good reason" in the EPDS was not sensitive to their situation. The measure is standardised for screening new

mothers (Cox et al., 1987) and has good clinical acceptability (Gemmill et al., 2006), but it is acknowledged that the use of postnatal screening tools in the NNU needs further research (Tahirkheli et al., 2014). Subsequent research may benefit from service user involvement to ascertain how mothers would prefer to document their progress with expressing milk, and how they could be asked sensitively about their mood.

Strengths and weaknesses

This feasibility study identified some difficulties that mothers may have with engaging with research while having an ill infant. This study differs from other NNU research as it asked mothers to engage in an intervention and another task over a pro-longed period of time. Other NNU research may not have difficulties with uptake because it may collect qualitative data, or requires mothers to give consent for an intervention for their infant and therefore does not add to demands for their time. This study is important because it highlights the need to consider the timing and accessibility of intervention when it is offered to mothers who infants within the NNU. Future research may benefit from the use of an app to make using an intervention and monitoring progress less time consuming.

A limitation is that the study did not identify how many mothers were in the unit and not expressing. This could help future researchers formulate staff capacity and determine who is best placed to introduce research to mothers. A further limitation of the study was that no specific questions were asked as to why mothers did or did not want to participate due to ethical principles. Another limitation is that data was only available for the few mothers who voluntarily provided information during the final stages of recruitment. This leaves the possibility that data on recruitment could be biased as only a small amount of

mothers gave reasons for not participating directly to the research team. Furthermore, there was limited data about the majority of mothers in the unit during this time who chose not to take part. Further demographic information (e.g. infant severity of illness, mothers age) may have been helpful to speculate further about reasons for non-participation. Another limitation was the limited time available to work on the project. Due to the constraints of a weekly research day across two sites, and mothers not always being available, it was difficult to meet and speak to all eligible mothers and staff about participation.

To conclude, this feasibility study has identified maternal factors which are important to consider for future research which could inform evidence based practice. It highlighted that within a busy NNU it was difficult to engage mothers in a relaxation trial when it was promoted with written information. Mothers who chose to participate had a conversation with a member of staff before giving consent. All mothers who used relaxation reported they would recommend it to other mothers, but did not believe the relaxation helped them feed their infant. It is important that future research is conducted in this area to determine if mothers' emotional wellbeing and milk production can benefit from the use of relaxation during this phase of motherhood, as this has the potential to protect infants from further ill health (Horta and Victora, 2013; Underwood, 2013). It is worthwhile for future research of interventions to consider the timing of the implementation of support, how accessible the support is and how much additional effort mothers' need to put in to observe any potential benefits for their infant and themselves.

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Appendices

Appendix 1.1: Author Guidelines for the Journal of Reproductive and Infant Psychology

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Journal of Reproductive and Infant Psychology is an international, peer reviewed journal, publishing high-quality, original research. Please see the journal's Aims & Scope for information about its focus and peer-review policy.
Please note that this journal only publishes manuscripts in English.

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Please include a word count for your paper. A typical article for this journal should be no more than 3500 words; this limit does not include tables, references, figure captions, endnotes.

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Please refer to these style guidelines when preparing your paper, rather than any published articles or a sample copy.
Please use British -ise spelling style consistently throughout your manuscript.
Please use single quotation marks, except where 'a quotation is "within" a quotation'. Please note that long quotations should be indented without quotation marks.

Please follow any specific Instructions for Authors provided by the Editor of the journal, which are available on the journal pages at www.tandfonline.com. Please also see our guidance on putting your article together, defining authorship and anonymizing your article for peer review.

We recommend that you use our templates to prepare your article, but if you prefer not to use templates this guide will help you prepare your article for review.

If your article is accepted for publication, the manuscript will be copyedited and typeset in the correct style for the journal.

Font: Times New Roman, 12 point, double-line spaced. Use margins of at least 2.5 cm (or 1 inch).

Title: Use bold for your article title, with an initial capital letter for any proper nouns.

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2. Second-level headings should be in bold italics, with an initial capital letter for any proper nouns.
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4. Fourth-level headings should be in bold italics, at the beginning of a paragraph. The text follows immediately after a full stop (full point) or other punctuation mark.
5. Fifth-level headings should be in italics, at the beginning of a paragraph. The text follows immediately after a full stop (full point) or other punctuation mark.

Tables and figures: Indicate in the text where the tables and figures should appear, for example by inserting [Table 1 near here]. The actual tables should be supplied either at the end of the text or in a separate file. The actual figures should be supplied as separate files. The journal Editor’s preference will be detailed in the Instructions for Authors or in the guidance on the submission system. Ensure you have permission to use any tables or figures you are reproducing from another source.

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References

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Checklist: what to include

1. **Author details**. Please ensure everyone meeting the International Committee of Medical Journal Editors (ICMJE) requirements for authorship is included as an author of your paper. Please ensure everyone meeting the International Committee of Medical Journal Editors (ICJME) requirements for authorship is included as an author of your paper. Please include all authors' full names, affiliations, postal addresses, telephone numbers and email addresses on the title page. Where available, please also include ORCID identifiers and social media handles (Facebook, Twitter or LinkedIn). One author will need to be identified as the corresponding author, with their email address normally displayed in the article PDF (depending on the journal) and the online article. Authors' affiliations are the affiliations where the research was conducted. If any of the named co-authors moves affiliation during the peer-review process, the new affiliation can be given as a footnote. Please note that no changes to affiliation can be made after your paper is accepted. Read more on authorship.

2. A structured **abstract** of no more than 250 words. A structured abstract should cover (in the following order): Objective, Background, Methods (to include design and participants), Results, and Conclusion.
3. **Graphical abstract** (Optional). This is an image to give readers a clear idea of the content of your article. It should be a maximum width of 525 pixels. If your image is narrower than 525 pixels, please place it on a white background 525 pixels wide to ensure the dimensions are maintained. Save the graphical abstract as a .jpg, .png, or .gif. Please do not embed it in the manuscript file but save it as a separate file, labeled GraphicalAbstract1.
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In order to be published in a Taylor & Francis journal, all clinical trials must have been registered in a public repository at the beginning of the research process (prior to patient enrolment). Trial registration numbers should be included in the abstract, with full details in the methods section. The registry should be publicly accessible (at no charge), open to all prospective registrants, and managed by a not-for-profit organization. For a list of registries that meet these requirements,

please visit the WHO International Clinical Trials Registry Platform (ICTRP). The registration of all clinical trials facilitates the sharing of information among clinicians, researchers, and patients, enhances public confidence in research, and is in accordance with the ICMJE guidelines.

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Please ensure that all research reported in submitted papers has been conducted in an ethical and responsible manner, and is in full compliance with all relevant codes of experimentation and legislation. All papers which report *in vivo* experiments or clinical trials on humans or animals must include a written statement in the Methods section. This should explain that all work was conducted with the formal approval of the local human subject or animal care committees (institutional and national), and that clinical trials have been registered as legislation requires. Authors who do not have formal ethics review committees should include a statement that their study follows the principles of the Declaration of Helsinki.

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All authors are required to follow the ICMJE requirements on privacy and informed consent from patients and study participants. Please confirm that any patient, service user, or participant (or that person's parent or legal guardian) in any research, experiment, or clinical trial described in your paper has given written consent to the inclusion of material pertaining to themselves, that they acknowledge that they cannot be identified via the paper; and that you have fully anonymized them. Where someone is deceased, please ensure you have written consent from the family or estate. Authors may use this Patient Consent Form, which should be completed, saved, and sent to the journal if requested.

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Appendix 1.2: Search Strategy

(1) “Intensive Care, Neonatal/” OR “exp Intensive Care Units, Neonatal/” OR “exp Pregnancy Complications/px [Psychology]” OR “exp Premature Birth/px [Psychology]” OR “exp Pregnancy Complications/th [Therapy]” OR “exp Infant, Premature/” OR “premature.tw.” OR “(pregnancy adj5 complication* adj5 psycholog*).tw” OR “((premature or preterm) adj5 (birth or delivery) adj5 psycholog*).tw.” OR “(pregnancy adj5 complication* adj5 therapy).tw.” OR “scbu.tw.” OR “special care baby unit.tw” OR “((infant or new born) adj5 (SCBU or "special care baby unit")).tw” OR “(neonatal adj5 (ICU or "intensive care unit")).tw”,

AND

(2) “exp "Imagery (Psychotherapy)"/” OR “exp Relaxation Therapy/” OR “(Progressive musc* adj5 relaxation).tw” OR “PMR.tw.” OR “((Deep or Rhythmic) adj2 breath* adj5 (relax* or technique)).tw.” OR “(relax* adj5 (strategy or intervention)).tw.” OR “Relaxation exercise*.tw” OR “autogenic therapy.tw” OR “autogenic training.tw.” OR “relaxation.tw.” (relaxation adj5 (therapy or intervention)).tw” OR “("relaxation therapy" adj5 mother*).tw”

AND

(3) “mother*.tw” OR “father*.tw” OR “parent*.tw”

Appendix 1.3: Risk of Bias Judgements

Feher, Berger, Johnson, and Wilder (1989)

Domain	Judgement	Justification
Random sequence generation	Unclear risk	"the women were randomly assigned to the intervention or comparison groups". Comment: no further information provided.
Allocation concealment	Unclear risk	No description of how allocation is informed is provided.
Blinding of participants and personnel	High risk	No description. Comment: Due to the nature of the intervention participants cannot remain blind, no description of staff awareness to allocation. There is an increased possibility of bias due to the possibility of variation of support provided by staff as this was not measured. "All mothers received routine supportive care from the nursing and medical staff, including verbal and written instruction concerning the use of the electric breast pump".
Blinding of outcome assessments	High risk	No description provided. Comment: No detail provided about the circumstances around the collections of the "post intervention" expression of breast milk. Techniques such as warming the breast and massage could have been applied prior to expressing.
Incomplete outcome data	Low risk	Reasons for failing to complete the study stated and even across groups.
Selective reporting	Unclear risk	No proposal available to review.
Other sources of bias	Low risk	No other sources of bias identified.

Fotiou et al. (2016)

Domain	Judgement	Justification
Random sequence generation	Low risk	"the participants were randomised and assigned by a nurse into two groups using the Integer Generator Free software, which produces random numbers in configurable intervals".
Allocation concealment	Unclear risk	No description provided.
Blinding of participants and personnel	High risk	No blinding described. Comment: As researcher had direct contact with participants and sharing information at the point of intervention it is judged that there is a high risk of bias.
Blinding of outcome assessments	Low risk	No blinding described. Comment: Risk is deemed to be low as parents completed self-report standardised questionnaires. "standardised questionnaires were mailed to the parents by the first author, following respective telephone arrangements and were collected the following day".
Incomplete outcome data	Unclear risk	Number randomised into each group not provided. "At the end of the study period, seven participants were excluded from further analysis due to lack of full compliance".
Selective reporting	Unclear risk	No proposal available to review.
Other sources of bias	Low risk	No other sources of bias identified, no conflict of interest declared.

Karbandi et al. (2015)

Domain	Judgement	Justification
Random sequence generation	High risk	"The sampling method was as randomly in two blocks of 2 months. So that the first toss will determine which group is sampled. Based on this method sampling was performed at first in the case group and then in the control group".
Allocation concealment	High risk	"Based on this method sampling was performed at first in the case group and then in the control group".
Blinding of participants and personnel	High risk	No blinding described. Comment: As researcher had direct contact with participants and sharing information at the point of intervention it is judged that there is a high risk of bias.
Blinding of outcome assessments	Low risk	No description of blinding of outcome measures. Comment: mothers completed standardised self-report measures (Pittsburgh Sleep Index Questionnaire). As both groups received some supportive information believed to lower the risk of bias.
Incomplete outcome data	Unclear risk	"From 66 mothers who were enrolled in the study, four mothers because of lack of desire to continue to participation in the study and two patients because their baby died were excluded". Comment: Explanation given, but no indication of which groups the mothers who did not wish to continue to participate were allocated to.
Selective reporting	Unclear risk	No proposal available to review.
Other sources of bias	Low risk	No other sources of bias identified, no conflict of interest declared.

Keith, Weaver and Vogel (2012)

Domain	Judgement	Justification
Random sequence generation	Low risk	"Mothers who chose to participate were randomized into 4 groups, using simple randomization, on the basis of a randomization schedule".
Allocation concealment	Unclear risk	No description provided.
Blinding of participants and personnel	Low risk	No description provided. Comment: Due to nature of the intervention participants cannot remain blind, but unlikely to impact on physiological outcomes.
Blinding of outcome assessments	Low risk	"Data collectors performing the Creamatocit measurement were blinded to group membership of the participants". Comment: Mothers self-reported daily milk volumes and submitted at the end of participation.
Incomplete outcome data	Unclear risk	No mention of incomplete outcome data. Comment: "Mothers of 162 infants completed the study" only 160 mothers are included in outcome data table.
Selective reporting	Unclear risk	No proposal available to review.
Other sources of bias	Low risk	No other sources of bias identified, no conflict of interest declared.

Appendix 2.1: Power Calculation Explanation

Through verification of the initial power calculation it was noted by the researcher that the calculation as documented in the project proposal contained an error. The initial power calculation was based on, Feher et al. (1989) which had a conservative correlation between measures (0.5) and used mean milk based on one measurement on day 7 to determine the effect size.

Through completion of a more in-depth review of the literature, it was noted that Keith et al.'s (2012) music and relaxation groups was the most appropriate to use for the calculation, given the similarity in study design and number of milk measurements. In agreement with a biostatistician, a secondary calculation was completed. The second calculation noted a difference of 6 participants to the original calculation. The primary aim of the study was to determine if it was feasible to recruit and engage mothers with the use of relaxation. As the target of sample size was not achieved, this does not impact to the ability to interpret the data.

Appendix 2.2 Recruitment Strategy

There were two changes to the recruitment strategy which were informed by feedback from staff and discussions with the research team. Figure 2.11.1 summarises the changes at each stage and the respective number of participants recruited during each stage.

Initially the study was promoted via the use of posters in family areas and waiting areas and by participant information booklets which were left by the infant's bedside. Nursing staff were encouraged to highlight the study information to mothers. The study was included in the staff safety brief at the start of each shift. Initial feedback from staff suggested that the posters and information appeared "too clinical". Following this feedback, new posters were distributed (Appendix 2.4), the layout and design of the participant information sheet was changed and the site in NHS A&A opened. It was also noted that it was difficult to ascertain mothers' reactions to the study information due to shift patterns, quantity of staff and allocated research time. Following ethical approval, the main researcher was then able to directly approach mothers. Where mothers volunteered a reason as to why they did not want to take part it was recorded in writing by the researcher.

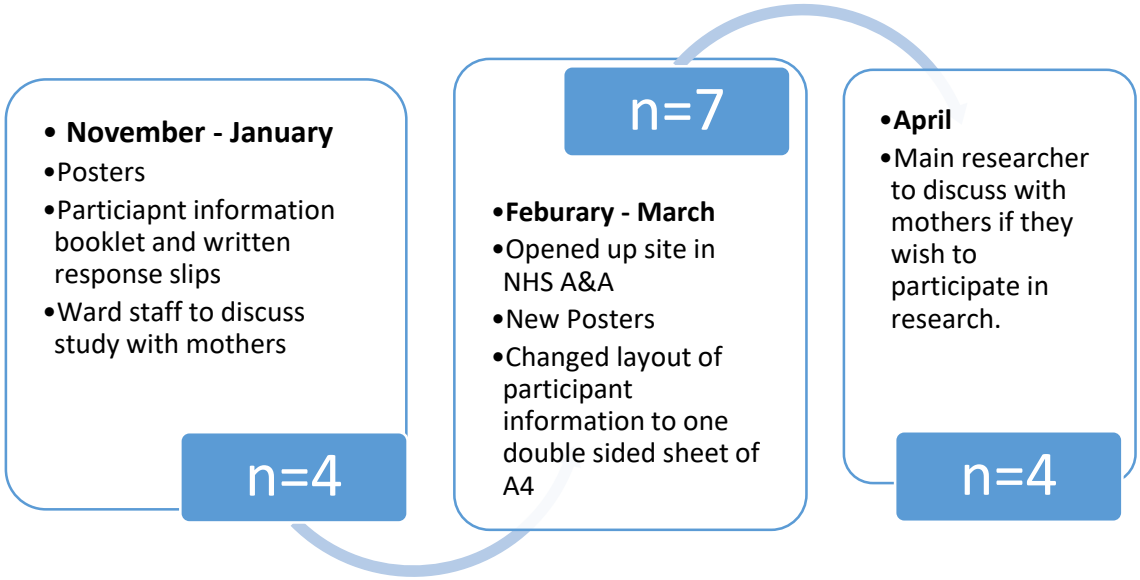

Figure 2.11.1. The changes to the recruitment strategy with the number of participants recruited during each phase

Appendix 2.3 Posters

NHS Greater Glasgow and Clyde

University of Glasgow

REcLINE Study

Effects of **Re**laxation on **L**actation levels **i**n **Ne**onatal Units

Having a baby admitted to the neonatal unit can be an extremely stressful time for mothers. This research is exploring how we can support mothers who wish to provide breast milk for their infants, as well as how we may be able to emotionally support mothers.

- Do you have a baby admitted to the neonatal unit?
- Are you expressing breast milk for your baby?
- Are you interested in taking part in research to help develop our understanding of breast milk expression?

If you have answered yes to all of the above questions.... please let a member of the nursing staff or Clinical Psychology Neonatology Team know, if you are interested in taking part in the REcLINE project.

Thank You ☺

v1 4th April 2016

NHS Ayrshire & Arran

University of Glasgow

TIME TO RELAX!

We're looking to see if **relaxation** can help Mums who are trying to express **breast milk**.

If you are expressing breast milk and would like to take part, please:

- Ask your nurse for a ReCLINE booklet
- Fill in the reply slip and hand it in

and we will be in touch.

Thank You ☺

The ReCLINE Study

REcLINE- Relaxation Effects on Lactation Levels in Neonatal Units

V2 DATE 06/12/2016

Appendix 2.4 Copy of Ethical Approval

WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

Miss Alison Brown
Trainee Clinical Psychologist
NHS Ayrshire and Arran
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1055 Great Western Road
G12 0XH

West of Scotland REC 5
West of Scotland Research Ethics Service
West Glasgow Ambulatory Care Hospital
Dalnair Street
Glasgow
G3 8SW

Date 22 March 2017

Direct line 0141 232 1804
E-mail WoSREC5@ggc.scot.nhs.uk

Dear Miss Brown

Study title: **A Feasibility Study Exploring the Relaxation Effects on Lactation Levels and Maternal Well-being in a Neonatal Unit**
REC reference: **16/WS/0169**
Amendment number: **v6 (REC Ref AM05 SA)**
Amendment date: **07 March 2017**
IRAS project ID: **205988**

Summary of Substantial Amendment: Change to protocol, approaching mums in the NNU and extension to recruitment date until June 2017.

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Notice of Substantial Amendment (non-CTIMP)	v6 (REC Ref AM05 SA)	07 March 2017
Research protocol or project proposal [Clean]	6	07 March 2017
Research protocol or project proposal [Tracked]	6	07 March 2017

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

16/WS/0169:	**Please quote this number on all correspondence**

Yours sincerely

On behalf of
Dr Stewart Campbell
Chair

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Dr George Bakirtzis, NHS Greater Glasgow & Clyde*
Dr Alison Graham

Appendix 2.5: Demographic Questionnaire

Maternal Demographic questionnaire

A little about you

1. What is your age (years)? _____

2. How far away do you stay from the hospital?
   - ☐ I currently stay at the hospital
   - ☐ I live within 5 miles of the hospital
   - ☐ I live between 6-10 miles of the hospital
   - ☐ I live between 11-15 miles of the hospital
   - ☐ I live more than 16 miles away from the hospital

3. What is your postcode?

   _____

4. How difficult do you find it travelling to the hospital (this may be due to time, method of travel, cost of travel)?
   - ☐ I don't need to travel to the hospital
   - ☐ I have no difficulties with travelling to and from the hospital
   - ☐ I have some difficulties with travelling to and from the hospital
   - ☐ I have many difficulties with travelling to and from the hospital

5. Did you have multiple births (twins, triplets)
   - ☐ No
   - ☐ Yes

6. Do you have any other children?
   - ☐ No
   - ☐ Yes, I have _____ (number of other children, not including the newest arrival(s))

   A. If you have other children did you breast feed them?
      - ☐ No
      - ☐ Yes
      - ☐ It was different for different children

7. Do you have a medical condition that you have been told may affect your breast milk supply?
   - ☐ No
   - ☐ Yes, but I would prefer not to say what it is
   - ☐ Yes, I have

     _____
     _

8. Are you taking any medication that you have been told may affect your milk supply?
   - ☐ No

- ☐ Yes, but I would prefer not to say what it is
- ☐ Yes, I am taking _____

9. Have you ever had psychological input the in the past?
   - ☐ No
   - ☐ Yes
   - ☐ I would prefer not to say

10. How many days have you been expressing milk for (including today)? _____

11. Have you attended the breastfeeding club?
   - ☐ No
   - ☐ Yes

12. Have you been able to express for the recommended 8-10 times in 24 hours
   - ☐ Never
   - ☐ Sometimes
   - ☐ Everyday

13. Prior to the birth of baby what were your feeding goals? (please tick one in each column)

☐ I wanted baby to just have breast milk	☐ I wanted baby to just feed from the breast
☐ I wanted baby to just have formula milk	☐ I wanted baby to just feed from the bottle
☐ I wanted baby to have both formula and breast milk	☐ I wanted baby to feed from both the bottle and breast

14. Now baby is here what are your feeding goals (please tick one in each column)

☐ I want baby to just have breast milk	☐ I want baby to just feed from the breast
☐ I want baby to just have formula milk	☐ I want baby to just feed from the bottle
☐ I want baby to have both formula and breast milk	☐ I want baby to feed from both the bottle and breast

----------Thank you for completing the questionnaire ----------

Appendix 2.6: Information to Extract from Infant Medical File

Participant # _____

Gestational age _____ weeks _____days

Baby birth weight _____lbs

Apgar score at birth _____

Nature of infant intervention

_____
_____
_____

Known medical diagnosis

_____
_____
_____
_____

Total number of times infant tried at the breast in 14 days

_____

Total Number of times feeding topped up by expressed milk in 14 days

_____

Total Number of times feeding topped up by formula milk in 14 days

_____

Appendix 2.7: Maternal Measurement of Feeding Goals

What are your **current** feeding goals (please tick one in each column)?

- ☐ I want baby to just have breast milk
- ☐ I want baby to just have formula milk
- ☐ I want baby to have both formula and breast milk

- ☐ I want baby to just feed from the breast
- ☐ I want baby to just feed from the bottle
- ☐ I want baby to feed from both the bottle and breast

What are your **future** feeding goals (please tick one in each column)?

- ☐ I want baby to just have breast milk until they move onto solid foods
- ☐ I want baby to just have formula milk until they move onto solid foods
- ☐ I want baby to have both formula and breast milk until they move onto solid foods

- ☐ I want baby to just feed from the breast until they move onto solid foods
- ☐ I want baby to just feed from the bottle until they move onto solid foods
- ☐ I want baby to feed from both the bottle and breast until they move onto solid foods

Appendix 2.8: Intervention Feasibility Questionnaire

Please tick the box which best represents how much you agree with the following statements…	**Strongly Disagree**	**Disagree**	**Neither agree nor disagree**	**Agree**	**Strongly Agree**
Q1: I felt calmer after I had used the relaxation practice					
Q2: I found the relaxation practice easy to use					
Q3: I found receiving text reminders to use the relaxation practice helpful					
Q4:I believe completing relaxation helped me to feed my baby					
Q5: I found it easy to fit the relaxation practice into my daily routine					
Q6: I believe the relaxation practice helped me maintain my feeding goals for my baby					
Q7: I would recommend the use of relaxation to other mothers who wish to express breast milk					

How often did you use the relaxation practice?	□ 0-4 times □ 5-9 times □ 10 or more times
When did you usually complete the relaxation practice? (*tick as many that apply)*	□ When expressing breast milk □ When visiting baby, with skin to skin contact with baby □ When visiting baby, without skin to skin contact □ At home
What could be improved with the relaxation intervention (the practice or text reminder)?	
Any other comments?	

Appendix 2.9 **Milk expression log** (blank replica)

Today's date _____

My Baby weights _____

My Baby Feeds

Every 2 hours

Every 3 hours

responsively

Today

Yes or No I visited the neonatal unit to be with my baby

Yes or No We did Kangaroo care

Yes of No My baby tasted drops of milk at breast

Yes or No My baby took a feed at the breast

Milk Sample	1	2	3	4	5	6	7	8	9	10
Time pumping started										
Time pumping ended										
Amount of milk from Left Breast										
Amount of milk from Right Breast										
Number of containers used										
Place pumped (home, NNU)										

Today I pumped a total of _____ times, and got _____mls of milk for my baby.

Things I want to remember about today_____

_____

_____

Personal Expressing Log

Appendix 2.10: Participant information sheet

Relaxation Effects on Lactation levels in Neonatal Units

This leaflet has been given to you by the Neonatal Unit, at the Royal Hospital for Children *on behalf of Alison Brown (Trainee Clinical Psychologist).*

Please would you take a few minutes to read this information.

As part of my Doctorate in Clinical Psychology, with the University of Glasgow, I am undertaking a research project in partnership with the Neonatal Unit at the Royal Hospital for Children**.** This leaflet provides you with all of the information you will need to decide whether you would like to participate in the study. If there is anything that you would like to discuss, please do not hesitate to contact me.

What is the study about?

I am interested in looking at if relaxation can help mother's emotional wellbeing and expression of breast milk.

Why am I being asked to take part?

You are being asked to take part because you are the mother of a baby who has been admitted to the neonatal unit. If you plan to express breast milk for your baby, I would like to invite you to take part.

Do I have to take part?

No, you do not have to take part in the study and deciding not to take part will not affect your baby's care in any way. You can withdraw from the study at any point without this affecting you or your baby's care.

What would I have to do?

If you agree to take part in the study, the main researcher, Alison Brown will contact you to arrange an initial meeting. You will then be asked to sign a consent form. You will be asked to complete 3 questionnaires (one about you, one about your mood and one about stress levels). This will take approximately 20 minutes. You will be asked to repeat the mood and stress questionnaire on day 7 and day 14 of the project which will take approximately 10 minutes. The measures will be reviewed as they may indicate some feelings of low mood or depression. This is for your safety and will offer you the opportunity to talk to someone if you are finding things difficult. I will ask to copy your entries from your expression log, which are given to all mothers in the unit, from the 14 days when you are participating in the study.

Half of mother will be allocated to a relaxation intervention and half will be allocated to a treatment as usual. The main researcher will have no control over which group you are allocated to.

If you are allocated to the relaxation intervention, you will be asked to complete a relaxation practice that will last for approximately 15 minutes. You can complete this practice at any time that best suits you and your family's needs. A daily text message will be sent to you to remind you to use the practice. At the end

of 14 days you will be given a questionnaire to share your opinion about the intervention.

If you are allocated to treatment as usual you will continue to receive the standard care.

The researcher will call you 12 weeks after you have completed study to ask about your method of feeding your baby.

Who would know I was taking part?

The staff in the Neonatal Unit will know that you are taking part in the study, but the information that you provided would be kept confidential. All data collected will be anonymised in the research report. I would only have to break confidentiality if I became concerned that you or someone else was at risk of harm.

What will happen to the information I provide?

The questionnaire and data from your expression log will be put into an electronic database where it will be used for data analysis. The anonymous data will be stored on an encrypted password protected computer. Only my supervisors (Psychologists working in Royal Hospital for Children in Glasgow, Crosshouse Hospital and Glasgow University) and I will have access to the data. The information will be analysed and presented in the form of a report and submitted to the University of Glasgow in part fulfilment of the Doctorate in Clinical Psychology and for publication in a scientific journal. All participants will be provided with a summary of the results if they would like them.

Are there any benefits to taking part?

There is some research in America, to date to suggest a similar relaxation practice can help with mother's milk production, however, this has not been replicated yet in the UK. Relaxation is commonly used in the UK to help cope with stress and therefore there may be some personal psychological benefits if you are in the relaxation group.

The information that you provide will add to our understanding of strategies that may be helpful for other mothers in the future. If this study were published in a scientific journal, it would contribute to the wider research literature and could inform developments in the psychological care of mothers who are expressing milk for their infant.

Are there any down sides to taking part?

The questionnaire asking about your mood may highlight that you are having some difficulties with your emotional wellbeing. You will be offered to speak to a trained member of staff if this is the case.

Who has reviewed the study?

The study has been approved by the University of Glasgow, the West of Scotland Research Ethics Committee and the NHS GG&C Research and Development Team.

Who do I contact for more information?

You may contact any of the researchers involved in this study if you have further questions about the research. An independent contact person is also available to provide information about taking part in research. Contact details can be found at the end of this leaflet.

What do I do now?

If you are interested in taking part in the study, please :

- **complete the attached form at the end of the leaflet and return it in the envelope to the nursing station or Clinical Psychologist.**

I will then contact you by your preferred method to answer any questions that you may have about the study and to arrange the initial appointment.
Thank you for taking the time to read this leaflet and for any further input you may wish to have.

Alison Brown (Trainee Clinical Psychologist)
Address: Mental Health and Wellbeing, University of Glasgow, Gartnavel Royal Hospital Academic Centre, 1055 Great Western Road, G12 0XH
Email: a.brown.4@research.gla.ac.uk
Telephone: 0141 211 0607

Contact information:

Name	Role	Email	Telephone
Dr Alison Jackson	Academic Supervisor	Alison.Jackson@glasgow.ac.uk	0141 211 3917
Dr Joan Burns	GG&C Clinical Supervisor	Joan.burns@ggc.scot.nhs.uk	0141 232 4333
Professor Andrew Jahoda	Independent contact	Andrew.Jahoda@glasgow.ac.uk	0141 211 0282

Please tear this page out and give it to a member of the nursing staff on the ward.

REcLINE Study

Relaxation Effects on Lactation levels in Neonatal Units

My name is _____ and I am interested in finding out more about the REcLINE study

I am happy to be contacted *(Please tick all that apply)*

o in person on the ward

o by telephone, my number is: _____

Signed: _____

Appendix 2.11: Consent Form

Title of study: **Relaxation Effects on Lactation levels in Neonatal Units**

Name of researcher: Alison Brown (Trainee Clinical Psychologist)

Please initial each box:

I confirm that I have read and understood the *Participant Information Leaflet (Version_____)* for the above study. ☐

I have had the opportunity to ask questions and have had satisfactory answers to these. ☐

I understand that my participation is voluntary and that I am free to withdraw at any time and without giving any reason. If I do withdraw from the study my or my infant's continued care will not be affected. ☐

I understand that only Alison Brown and the supervising Psychologists (Dr Alison Jackson, University of Glasgow and Dr Joan Burns, Maternity & neonatology Clinical Psychology Service, NHS GG&C) will have access to the information that I provide. ☐

I understand that my and/or my infant's medical care or legal rights will not be affected by taking part. ☐

I understand that Alison Brown or nursing staff may contact a member of the ward Clinical Psychology team if I score highly on measures of mood. ☐

I give permission for the researcher to inform the Neonatal Unit, Royal hospital for Children of my involvement in this study by letter, which will include my infant's name and date of birth. ☐

I understand that sections of my medical notes may be looked at by the research team, where it is relevant to my taking part in the research, and by authorised representatives of the sponsor and NHS Greater Glasgow and Clyde, for the purposes of audit only. I give my permission for the research team to have access to my records. I understand that anonymised information may be transferred to personnel out with the research team for analysis. ☐

I would like to receive a summary of the project findings once it is completed (estimated completion date December 2017). Please send a copy to me at the following address: ☐

_____

I agree to take part in the above study.

Name of Participant		Signature	
Date			
Name of Researcher		Signature	
Date			

Appendix 2.12 Reasons to not take part

Group	Subgroup	Comment
Transition (n=4)		"I'm thinking about going home now" (Angela) Not interested in taking part, "I'm going home soon" (Becca) About to transfer home and mum focusing on that so did not want to take part in NNU activity (Kim) Mum not in NNU when agreed to complete consent 3 times. When met with mum plans for discharge home were taking place. (Louise)
Time (n=9)		"I don't think it's for me I don't have the time" (Eve) "It would be another thing to think about that I don't have time for …" (Grace) "I don't have enough time to do the study" (Mary) "I will do it, if I don't have to fill in the expression log, I don't have time to do that with everything else you have to do when expressing". (Natasha) "I just don't want to listen to relaxation at night", it was explained that mum could do relaxation at any time "No I don't want to take part". (Olga) mum reported she didn't feel she wanted to devote time to something else at present. (Penny)
	Too many demands (n=3)	"so much information might have seen it, I can't remember so leave another copy with me". Agreed to meet again. "It's so overwhelming in here still no chance to read it yet, if you come back in a couple of days" Not in on future returns. (Daisy) "… there's too many other things going on in my head just now" (Francesca) "I don't want to take part because it'll be another thing that I have to do, I think it could add to my stress levels". (Ingrid)
Lack of Need (n=4)	Coping	"it's not for me I'm coping ok doing other things" (Chloe) "Not struggling to get milk …" (Francesca)
	Applying other techniques (n=2)	"I used hypnobirthing and still applying those techniques. I'm not struggling so will decline". (Heather) "I have already been given relaxation this week so I'll just use that" (Jane)
Technology		"… I don't have a CD player" (Grace)

Appendix 2.13 Relaxation comments and suggestions for improvement

P#	Improvement comments	Any other comments	Coding
Terri	no comment	look at the cd being available to use on iPhone/iPad	(1)
Felicity	no comment	This would be great study for woman with no so busy lifestyles	(2)
Sarah	(Text reminder not useful*), an app with different relaxation methods for people to choose from would improve the intervention	I struggled to fit the relaxation into daily feeding routines as well as juggling travelling/attending to babies cares	(1), (2) (3)
Naïve	Perhaps an MP3 version that could be downloaded onto a phone?	I enjoyed the relaxation techniques	(1) (4)
Tracy	if music was on longer felt that the lesson wasn't long enough	no comment	(3.1)
Fiona	no, for the time I got to use the practice it was good	no keep going	(4)

Coding key

Code	Theme	Count	Combined Count
1	Technology	n=3	n=3
2	Time	n=2	n=2
3	More variation of practice	n=1	n=2
3.1	Length of practice	n=1	
4	Positive regard	n=2	n=2

*Not coded as data already captured through Q3 of the feasibility questionnaire.

Appendix 2.14: Full distribution of mothers feeding goals

Mothers reported preferred method of feeding over time in the TAU and relaxation group

		TAU	Relaxation
Previous	Just breast	2 (50%)	2 (50%)
	Just bottle	0	2 (28.6%)
	Both	4 (66.7%)	3 (42.9%
Day 1	Just breast	0	1 (14.3%)
	Just bottle	1 (16.7%)	3 (42.9%)
	Both	5 (83.3%)	3 (42.9%)
Day 14	Just breast	1 (16.7%)	0
	Just bottle	1 (16.7%)	6 (85.7%)
	Both	4 (66.7%)	1 (14.3%)
Future	Just breast	0	0
	Just bottle	1 (16.7%)	5 (71.4%)
	Both	5 (83.3%)	2(28.6%)

Mothers preferred source of milk for their infant over time in the TAU and relaxation group.

		TAU	Relaxation
Previous	Just breast milk	5 (83.3%)	5 (71.4%)
	Just formula	0	1 (14.3%)
	Both	1 (16.7%)	1 (14.3%)
Day 1	Just breast milk	0	1 (14.3%)
	Just formula	1 (16.7%)	3 (42.9%)
	Both	5 (83.3%)	3 (42.9%)
Day 14	Just breast milk	5 (71.4%)	2 (28.6%)
	Just formula	0	3 (42.9%)
	Both	1 (16.7%)	2 (28.6%)
Future	Just breast milk	6 (100%)	1 (14.3%)
	Just formula	0	4 (57.1%)
	Both	0	2 (28.6%)

Appendix 2.15 Major Research Project Proposal

Abstract

Background: Some infants are not able to feed from the breast due to the circumstance of their birth or subsequent health complications. A complex relationship between many factors influences a mother's decision to initiate and sustain breast feeding. Maternal expectations of feeding and ability to fulfil her plan have been found to be a risk factor for depression. Feeding in a neonatal unit has specific stressors, which may impact on maternal feeding practices. Audio relaxation interventions increased the quantity and quality of breast milk in mothers with infants in a Special Care Baby Units in the USA.
Aims: This project aims to identify if it possible to recruit and engage mothers in the use of an audio relaxation intervention. Furthermore, it aims to identify if the intervention impacts on lactation volumes, a mothers emotional wellbeing, frequency of expression, and perception of meeting her feeding goals.
Method: A random allocation (14-day relaxation intervention vs treatment as usual), repeated measures research design will be used. A priori power analysis indicates 36 participants are needed.
Applications: The outcomes of this research could result in a clinical recommendation that mothers in the neonatal unit should be encouraged to access to audio relaxation when engaging in milk expression.

Introduction

It is a recommendation by the World Health Organisation (WHO) that all infants should be fed exclusively breast milk from birth to six months (WHO, 2002). Some infants are not able to feed from the breast due to ill health. When babies are admitted to a Special Care Baby Unit (SCBU) or Neonatal Intensive Care Unit (NICU) mothers can express milk for their baby. This can provide long term protective properties (Horta & Victoria, 2013; Becker, Smith & Cooney, 2015) and is a predictor of infant survival in low birth weight infants (Boon, Puah & Lye, 2000).

Global research has identified that the choice to initiate and sustain breastfeeding is determined by a relationship between demographic (age, socio-economic status), physical (milk supply, infant and maternal health), social (societal beliefs about breastfeeding, experiences of health care, level of support) and psychological (maternal mental health,

interest and intention) factors (Thulier & Mercer, 2009; Ajetumobi & Whyte, 2012). This decision is further complicated for mothers with infants in Neonatal Units (NNU) where breastfeeding can be perceived to be a duty or the only thing mother can do to care for baby (Flacking, Ewald, Nyqvist, & Starrin 2006; Sweet, 2008). Separation between mother and baby in NNU can negatively impact on maternal emotional wellbeing, feeding practices, infant development and attachment (Flacking et al., 2012). Qualitative studies identified that strangers and staff nearby, a noisy and stressful environment, adjusting to the early arrival of baby (Nyqvist & Kylberg, 2008) and worries surrounding inadequate milk supply (Alves, Rodrgiues, Frage, Barros & Silva, 2013) negatively impact on maternal feeding experiences in NNU. One study in an English NNU reported that 76% of mothers initiated expression and by day 14 this dropped to 46% (Smith & Embleton, 2013).

UNICEF UK Baby Friendly Initiative (UNICEF, 2000) is the main intervention to promote breastfeeding for mothers**.** This is a set of evidence-based standards that are applicable to maternity, neonatal, health visiting, and children's services. A Cochrane review identified factors such as, the warmth of the breast, breast massage, expressing within the first hour post-birth and pumping more than four times per day has a positive effect on the quantity of milk of mothers with infants in NNU (Becker et al. 2015). Renfrew et al. (2009) systematic review of breastfeeding interventions, specific to NNU, found strong evidence that Kangaroo care (a skin to skin contact programme), and peer support were effective interventions for breastfeeding.

In two American randomised control trials, audio relaxation interventions were identified as having a positive effect on milk quantity in NNU (Feher et al., 1989; Keith et al., 2012). Relaxation is used as standard practice in psychological interventions to regulate emotions. Relaxation was used with mothers, due to the link between maternal stress and milk production. Oxytocin stimulates expression of breast milk (Stuebe et al., 2012) and stress negatively impacts on oxytocin levels (Niseen et al., 1996) thereby negatively impacting on production of breast milk. However, neither Feher et al. or Keith et al. measured mental wellbeing, therefore were unable to link maternal emotional wellbeing and lactation levels. Hill, Aldag, Chatterton, and Zinaman (2005) measured psychological distress, through a visual analogue scale, and lactation quantity in preterm and term mothers. They identified that mothers of preterm infants experienced greater psychological distress, but this did not

significantly relate to milk supply at 6 weeks postpartum. It is questioned whether this finding would be upheld had a standardised mood measure been employed.

Finally, Becker, et al. (2015) identified that research to date has negated to explore maternal goals for feeding their infant. A mother's expectation of feeding practices and the ability to fulfil her plan was identified as a risk factor for maternal depression (PND) (Borra, Lacovou, & Sevilla, 2014). The highest risk of PND was observed in mothers who planned to breastfeed but were unable to (Borra et al. 2014). This may be understood through Beck's psychological model of depression where a depressive episode is triggered by loss (Beck & Alford, 2008). The loss of feeding expectation and feelings of failure (Borra et al, 2014), may trigger depression. A predicted secondary gain from the relaxation intervention would be that mothers achieve their feeding goals, which may protect against the development of PND.

In summary, mothers of infants in NNU in the UK may find it difficult to sustain feeding their infant breast milk due to a number of factors detailed above. Further research is needed within the UK to help understand how services can support mothers who choose to express milk for their infant. Knowing if mothers are willing to engage in the consistent use of a relaxation intervention, and if the intervention; improves physiological processes, and psychological wellbeing would be beneficial for services to plan interventions.

Aims

The project aims to determine if it is possible to recruit and engage mothers to use an audio relaxation intervention. Furthermore, it aims to identify if following a relaxation intervention there is an increase in lactation volumes, an improvement in maternal emotional wellbeing, frequency of expression and perception of meeting her feeding goals.

Research Questions

Q1: Is it feasible to recruit mothers for 14 days to use an audio relaxation intervention and record their feeding volumes, frequencies and complete emotional wellbeing measures?

Q2: Do mothers who use an audio relaxation intervention have improved:

i) milk volume,

ii) emotional wellbeing

iii) frequency of milk expression

iv) adherence to their feeding goals.

Plan of Investigation

Participants

Participants will be mothers of babies admitted to the NNU in the Royal hospital for Children, Glasgow and Crosshouse Hospital Ayrshire and Arran (A&A).

Inclusion Criteria

Mothers (over 18 years old) of infants in NNU in NHS GG&C and NHS A&A, between approximately August 2016 and April 2017 who are fluent in English and wish to express breast milk will be invited to participate.

Exclusion Criteria

Mothers who are infected with HIV or tuberculosis, are engaging in any medical treatment or substance mis-use which negatively impacts on mother's milk quality or where there is a high chance of infant death (determined by medical team) will not be invited to participate.

Recruitment procedures

The names of babies and dates of admissions are placed on the electronic boards around the nursing station. I will review the board weekly and note down the names of babies and the dates of admission.

I will then approach nursing staff of the new arrivals and ask if mum is expressing. If mum is confirmed to be expressing I will ask nursing staff to check with mum if it is ok for me to approach mum. I would then approach mums and introduce the study to them. I would introduce the study in the context of being conducted through the Psychology department within the NNU for the completion of for my Doctorate in Clinical Psychology. I would ask mums if they had time to hear a bit about the study and if it's ok to leave information with them.

If mums indicate interest, (e.g stating they would like to take part, that they think it sounds interesting, that they want to think about it) I would ask them if it's ok to make an appointment time to come back and see them, once they had time to review the participant information (at least 24 hours later). If this is not ok, no further attempt to recruit would be

made. If mums agree to this, I would go back and ask if they do or do not want to participate. If mums do, I would take consent. If mums don't want to take part but volunteer a reason as to why, I would note down this reason in the screening log.

The mothers can discuss any questions they have about the research, with a minimum of 24 hours from receiving participant information to give written consent (see included documents).

Measures

Demographic data will be collected for each mother/infant pairing through a questionnaire (Appendix 1) and reviewing the baby's medical file (Appendix 2).

Mother's mood will be measured by the Edinburgh Post-Natal Depression Scale (Cox, Holden and Sagovsky, 1987) (EPDS) and the Parental Stressors Scale Neonatal Intensive Care (PSS-NICU) (Miles, 1989) at baseline, day 7 and day 14 as recommended by Becker et al. (2015).

EPDS (Cox, et al., 1987) - The EPDS (Appendix 3) is a postnatal depression screen, which asks mothers about their feelings over the past 7 days. The questionnaire is being repeatedly administered 7 days apart so there will be no overlap in time of rating. It is a 10-item self-report questionnaire. Scores range from 0 to 30, scores over 10 indicate the likelihood that a mother is experiencing distress. Scores of 12 and above will result in the mother being offered to speak to the departmental Clinical Psychologist (Cox et al., 1987). The EPDS is a reliable measure with an alpha coefficient of.87 (Cox & Holden, 2003).

*PSS-NICU- (*Miles, 1989) - The PSS-NICU (Appendix 4) is a 26 item scale investigating parent perception of stress. Parent's rate on a 5 point Likert scale of the degree of distress experienced in relation to infant appearance and parental role. The two subscales have an alpha coefficient of 0.92 (Miles et al., 2007).

Maternal measurement of feeding goals –Maternal feeding goals in the NICU can be transient (Hoben et al., 2015). Mothers will be asked the type of food and method of feeding, via a questionnaire (Appendix 5). On day 1 mothers are asked what their pre-delivery goals were, and what their current (post-delivery) goals are, on day 14 of the study

this will be asked about current and future goals (Hoben et al. 2015). Mothers will receive a call 12 weeks after day 14 to ask about current feeding.

Mother's experience of the intervention- At the end of their participation, mothers in the intervention arm will complete a questionnaire about their experience of the intervention (Appendix 6). The questionnaire explores feasibility concepts such acceptability, demand, implementation, practicality, and integration (Bowen et al., 2009).

As standard treatment mothers are given a booklet to record quantity of milk at each expression. This booklet gives information on expression and transition to breastfeeding and a diary section (Appendix 7). Mothers will complete this log and the researcher will copy the information for the 14-day period they are involved in the study. Infant feeding development is recorded in binary form (yes or no) in the diary. To gain more information about the frequency of support with feeding this information will be extracted from their baby feeding chart.

Design

To avoid selection bias, a random allocation, repeated measures research design will be used. Mothers will be randomly assigned to a treatment as usual (TAU), or a relaxation arm through block allocation using a computer programme. The academic supervisor will place allocation outcome in a sealed envelope. Block allocation, (blocks of 4), will be used to maintain an equal group size. Due to resource and practical limitations, once the participant is informed of their allocation the researcher will not remain blind.

Treatment as usual - Mothers in the TAU allocation will be given standard care. As mothers in the NNU currently have access to an American audio relaxation intervention, they will be asked to record the frequency of use.

Relaxation intervention - Mothers in the relaxation arm will have the above treatment in addition to access to a British audio recording of progressive muscular and imagery relaxation practices (Appendix 8) which will last approximately 15 minutes. Mothers can access the recording in the NNU and will be given a CD copy to take home. A daily text reminder will be sent to promote the use of the relaxation.

Research Procedures

After giving signed consent, mothers will complete baseline mood measures. So the researcher is blind to allocation to the point of gaining consent, mothers will be informed of their allocation by opening a sealed envelope. All mothers will complete the standard diary following each episode of expression for 14 days. The researcher will call the nurses to request that the EPDS and the PSS-NICU are completed with mothers on day 7 and 14. Completed copies of questionnaires and diaries will be held in the nurses file for safe storage and collected by the researcher at the earliest possible opportunity. Mothers will be contacted 12 weeks after their 14-day data collection and asked about their current method of feeding.

Data analysis

Following data collection, advice will be sought from the Robertson Centre statisticians about the best way to analyse the quantitative data (repeated measure ANOVAs, VS, regression analysis). The intervention arm is the independent variable. The dependent variables are milk quantity, frequency of milk expression, EPNDS and PSS-NICU score. CHI^2 analysis will be used to analyse mother's adherence to their feeding goals.

Justification of sample size

Feher, et al. (1989) found an effect size of d=0.6 for the relaxation intervention on milk quantity. A priori Power analysis ran through GPower (Erdfelder, Faul, & Buchner, 1996) indicated that if data are analysed using a repeated measures ANOVA, a total sample size of 24 would be needed to detect a medium (f=0.25) effect size, with an alpha .05, and power at 0.80.

Feher, et al. (1989) reported that 77.5% (n=55) of participants completed the study. Participant's dropped out due to choice, infant death and transfer out of hospital. TAU in the NNU includes access to an audio relaxation track but is not actively encouraged, this may reduce the size of an effect if one is identified. Taking this dropout rate and the fact this is a feasibility study, the research team will aim to recruit 30 participants.

Settings and Equipment

The research will be completed within the NNU and mother's homes (when expressing at night). The researcher will meet mothers in the NNU for data collection at baseline and

collect measures from patient files at the end of the research. Mothers will have access to an mp3 player, headphones and a CD copy of the relaxation. Diaries are provided as standard care in the NNU.

7. Health and Safety Issues (Appendix 9)

Researcher Safety Issues

The lead researcher will meet with mothers on NHS GG&C and A&A property within working hours. Local health and safety procedures will be applied. The researcher will receive regular supervision from academic and clinical supervisors should difficulties arise.

Participant Safety Issues

Mothers who indicate high levels of distress or indicate a level of risk through the item asking "the thought of harming myself has occurred to me" of the EPDS will be offered to speak to the Clinical Psychology Neonatology team.

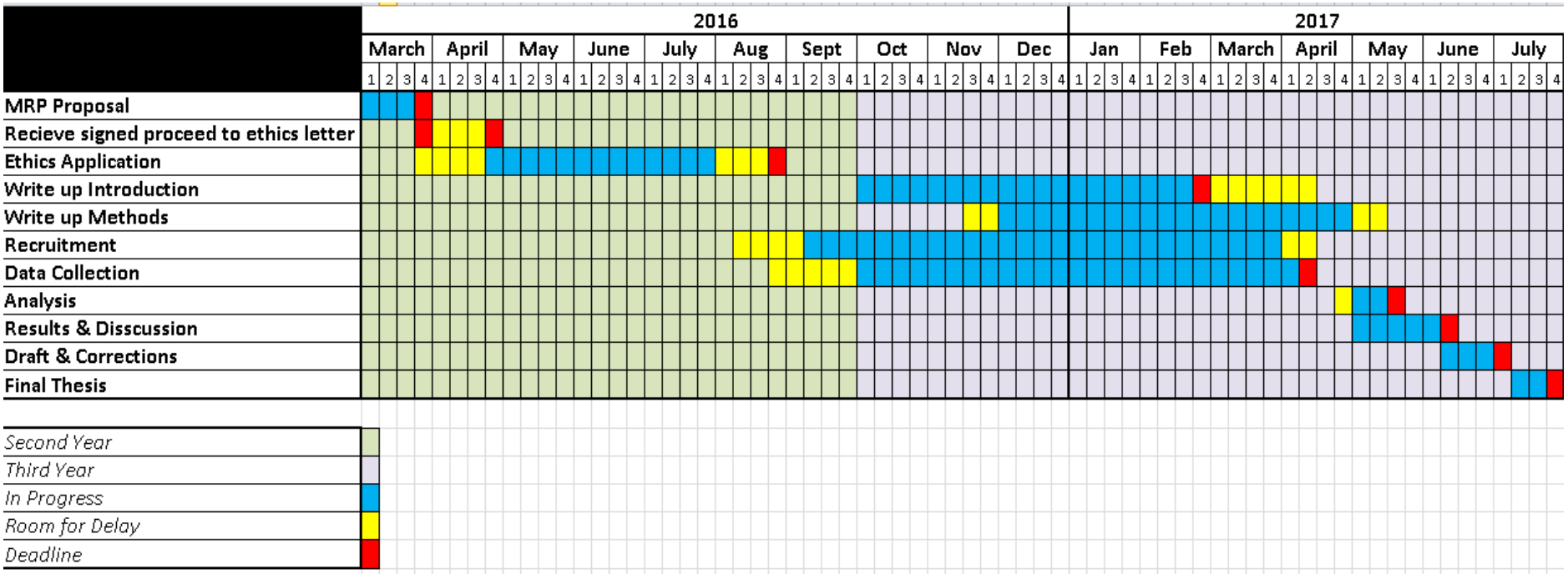
8. Ethical Issues

Ayrshire and Arran (A&A) R&D will be requested to be a sponsor with a memorandum of understanding set up with Glasgow University. A&A R&D will be contacted to complete an NHS to NHS pro-forma to gain access to participants in GG&C. An application for GG&C R&D site approval will be made and an application to IRAS will be submitted. IRAS will be submitted by June 2016. A&A R&D permission will be requested prior to opening a site in Crosshouse Hospital.

9. Financial Issues

The cost is expected to be £166.12. See Appendix 10.

10. Timetable



11. Practical Applications

The research will inform whether it is feasible for mothers to use the relaxation intervention and if this has a positive impact on milk quantity and emotional wellbeing. This will inform future research which could influence clinical practice. This would be helpful to support the baby friendly status of the Royal hospital for Children and other SCBU within the UK.

12. References

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Health and Safety form

WEST OF SCOTLAND/ UNIVERSITY OF GLASGOW
DOCTORATE IN CLINICAL PSYCHOLOGY
HEALTH AND SAFETY FOR RESEARCHERS

1. Title of Project	Effects of relaxation on lactation outcomes and maternal well-being in a neonatal unit
2. Trainee	Alison Brown
3. University Supervisor	Dr Alison Jackson
4. Other Supervisor(s)	
5. Local Lead Clinician	Dr Joan Burns (Consultant Clinical Psychologist)
6. Participants: (age, group or sub-group, pre- or post-treatment, etc)	Mothers of infants admitted to Special Care Baby Unit and allocated to Treatment as usual or relaxation intervention arm of the research.
7. Procedures to be applied (eg, questionnaire, interview, etc)	Mothers will be asked to complete demographic questionnaire, and feeding goals questions at the start of the research. The Edinburgh Post-natal Depression Scale (Cox, Holden & Sagovsky, 1987) and the Parental Stressors Scale Neonatal Intensive Care (PSS-NICU) (Miles,1989) will be completed at baseline, 7th day of intervention and the 14th (final) day of the intervention. Mothers will complete a diary that is given out as standard procedure in the neonatal units. They will record at each episode of milk expression. Mothers will be asked to record time pumping started, time pumping ended, amount of milk from breast, where they pumped, if they visited the neonatal unit that day, if they engaged in kangaroo care, and if the infant fed at

	the breast at all that day. As an addition, mothers will be asked to record how often they engaged with the relaxation material if they are allocated to that arm of the trial.
8. Setting (where will procedures be carried out?) i) Details of all settings	Mothers will complete questionnaires on hospital wards where staff can be approached if participants need to discuss questionnaire content. Mothers will be expressing at home and asked to complete the diary at home. Mothers will have access to the relaxation intervention at home and when they attend the hospital wards.
ii) Are home visits involved	No

WEST OF SCOTLAND/ UNIVERSITY OF GLASGOW
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HEALTH AND SAFETY FOR RESEARCHERS

9. Potential Risk Factors Considered (for researcher and participant safety): i) Participants ii) Procedures iii) Settings	i) Mothers will be asked to complete questionnaires which may indicate the need for additional support. The EPDS is a depression screen with scores above 12 indicating the potential that additional support is needed. Item 10 asks if mothers have thought about deliberately harming themselves. ii) There is a risk that breast expression machines if not fitted properly can cause physical harm to the breast iii) The research will be conducted within the ward

	where hospital machinery and infants families will be. There is potential for families to be experience heightened emotions due to their child's health status.
iv) . 10. Actions to minimise risk (refer to 9) a. Participants b. Procedures c. Settings	A) If item 10 is ticked or mothers score above 12 mothers will be guided to speak to a member of the clinical psychology team if they are not already doing so. B) As part of standard care, from nursing staff, mothers are supported to express milk. If mothers have difficulty with this, they are able to approach a member of the nursing team. C) GG&C Hospital health and safety policies will be followed. Families will be made aware they can speak to members of the clinical psychology team if they would like additional support.

Trainee signature: ..... Date: .....

University supervisor signature: ..... Date: .....

Cost and equipment form

RESEARCH EQUIPMENT, CONSUMABLES AND EXPENSES

Trainee …… ……

Year of Course ……Second……. **Intake Year**……2014……..

Please refer to latest stationary costs list (available from student support team)

Item	Details and Amount Required	Cost or Specify if to Request to Borrow from Department
Stationary	Envelopes (to indicate interest in participating) X DL box	Subtotal: 6.23
Postage		Subtotal: 0
Photocopying and Laser Printing (**includes cost of white paper**)	Participant info copies (100 copies = 400 sheets), consent form (100 copies = 200 sheets), notification to participate (100 copies = 100 sheets) demographic Q (50 copies = 100 sheets), baby info Q (50 copies= 50 sheets), Feeding goals Q (50 copies = 50 sheets) EPND (freely available) (150 copies = 150 sheets), PSS-NICU (free available) (150 copies = 300 sheets)	1350 sheets x 0.05 Subtotal: £67.50
Equipment and Software	Ipod shuffle for listening to audio relaxation intervention x 4 (£12.99 each) to buy. Headphones x2 (£9.99 each) to buy	Subtotal:£71.94
Measures		Subtotal: 0
Miscellaneous	Blank CD for audio recording to listen to intervention at home (25 blanks = £5.68) Text message reminder service for 25 participants. £0.06 per message. 14 messages over intervention = £21.00	Subtotal £26.68
Total		£166.12

For any request over £200 please provide further justification for all items that contribute to a high total cost estimate. Please also provide justification if costing for an honorarium:

Trainee Signature…… … Date……

Supervisor's Signature …….. Date ……